

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
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Monday, May 13, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, held at Weitz & Luxenburg PC, 3011
West Grand Avenue, Suite 2150, Detroit,
Michigan, commencing at 9:20 a.m., on the
above date, before Michael E. Miller, Fellow
of the Academy of Professional Reporters,
Registered Diplomate Reporter, Certified
Realtime Reporter and Notary Public.

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1 PROCEEDINGS

2 (May 13, 2019 at 9:20 a.m.)

3 (The following proceedings were
4 conducted off the videotaped record.)

5 MR. NICHOLAS: Before we get
6 started, Mr. Fuller, counsel for
7 plaintiffs, just handed me a Touhy
8 authorization letter that's dated
9 April 12th of 2019. This is the first
10 we've seen it. I'm going to proceed
11 with the deposition.

12 I will reserve our right to
13 come back if there's anything about
14 our receipt of this or something in
15 the letter that requires us to come
16 back and ask more questions since
17 we're seeing it for the first time,
18 and that's what I wanted to say.

19 MR. FULLER: Sure. And we'll
20 put on the record that as everyone
21 here knows, Mr. Rafalski is a former
22 DEA agent, therefore Touhy
23 authorization would have to be
24 obtained, similarly to the 20 former
25 DEA employees that the defendants

1 requested Touhy clearance on before
2 disclosing some of their expert
3 reports.

4 I've been asked to remind that
5 the DEA wasn't noticed of this depo,
6 even though he's a former agent, by
7 the defense. They weren't necessarily
8 happy with that. They asked for
9 everybody to comply with the Touhy
10 authorization, which, similar to the
11 other authorizations in this case,
12 allows the witness to testify to --
13 well, a little different with Rafalski
14 because he's reviewed a lot of the
15 documents produced by all the
16 defendants, testified from the
17 discovery produced in this case and
18 anything nonprivileged as set out in
19 the Touhy authorization.

20 MR. NICHOLAS: Okay. There's
21 too many things to argue about in this
22 case to get into a big argument --

23 MR. FULLER: Sure, sure.

24 MR. NICHOLAS: -- but I will
25 just say that he's your retained

1 expert. You've had this letter for a
2 month; you're just giving it to us
3 today.

4 So I don't get the part where
5 the DEA -- if the DEA is unhappy,
6 maybe they're unhappy with you guys,
7 but they shouldn't be unhappy with us
8 because he's your person.

9 But like I said, we don't need
10 to spend any more time on it.

11 THE VIDEOGRAPHER: Ready to
12 begin?

13 MR. NICHOLAS: I am.

14 (Whereupon the videotaped
15 record begins.)

16 THE VIDEOGRAPHER: We're now on
17 the record. My name is David Lane,
18 videographer for Golkow Litigation
19 Services. Today's date is May 13th,
20 2019. Our time is 9:22 a.m.

21 This deposition is taking place
22 in Detroit, Michigan in the matter of
23 National Prescription Opiate
24 Litigation. Our deponent today is
25 James E. Rafalski.

1 Counsel will be noted on the
2 stenographic record. Our court
3 reporter is Mike Miller, and he will
4 now swear in the witness.

5 JAMES E. RAFALSKI,
6 having been duly sworn,
7 testified as follows:

8 EXAMINATION

9 BY MR. NICHOLAS:

10 Q. Good morning, Mr. Rafalski. My
11 name is Bob Nicholas. I represent
12 AmerisourceBergen. I'm here to ask you
13 questions in connection with the MDL opioid
14 litigation and specifically the Track 1 and
15 Track 2 -- just the Track 1 cases that are
16 currently scheduled to go to trial in
17 October.

18 A. Good morning, sir.

19 Q. Good morning.

20 You are here as a retained
21 expert on behalf of the Track 1 plaintiffs in
22 this case; is that right?

23 A. Yes, sir, I am.

24 Q. Okay. And you are being paid
25 for your time?

1 A. Yes, sir, I am.

2 Q. Tell me what you're being paid
3 in terms of just what's your rate?

4 A. \$300 an hour.

5 Q. Okay. And is that for
6 everything you do or is that for -- just for
7 reviewing papers and in connection with your
8 report?

9 A. It's for everything I do.

10 Q. So are you -- you're not being
11 paid a different rate to testify?

12 A. Yes, sir.

13 Q. You are being paid a different
14 rate to testify?

15 A. Yes, for my deposition, or for
16 this deposition today, it's at \$500 an hour.

17 Q. Okay. And if there's a trial
18 and you testify at the trial, that would be
19 at \$500 an hour?

20 A. That's never been discussed, so
21 I don't know what rate that would be.

22 Q. Okay. Might be higher?

23 A. I would guess it at least will
24 be \$500 an hour.

25 Q. Sure. Tell me, if you could --

1 A. Could I make a little
2 correction to that?

3 Q. Sure, of course.

4 A. So when I first started, it was
5 at a \$200 rate. And then at some point I was
6 approached and it increased to 300. So my
7 initial rate was at \$200 an hour.

8 Q. When did you start?

9 A. August of 2017, I signed my
10 retainer.

11 Q. Okay. And so your August 2017
12 retainer had a rate of \$200 an hour?

13 A. Yes, sir.

14 Q. And how long was that your
15 rate?

16 A. Until -- I believe it was
17 October of 2018.

18 Q. Okay.

19 A. Either August or October of
20 2018.

21 Q. And you said you were
22 approached. What do you mean -- who
23 approached you?

24 A. Well, in discussions with one
25 of the attorneys, my original retainer

1 expired and we had some conversations about
2 my rate. It came to my attention that other
3 experts of at least equal skill were
4 receiving \$300 an hour, so when I brought
5 that topic up, there was an agreement to pay
6 me \$300 an hour.

7 Q. Okay. So it was in the form of
8 a negotiation; is that right?

9 A. Well, I guess you could
10 consider that. It was more of a
11 conversation, came up in conversation so
12 there was no need to negotiate. It was just
13 agreed upon when it was brought up.

14 Q. Okay. I'm going to get back to
15 the work you've done in a second, but let me
16 just ask you just a couple of basic questions
17 about yourself.

18 You were a police officer for a
19 number of years, right?

20 A. Yes, sir.

21 Q. Okay. How many years?

22 A. 27 total with two different
23 police departments, police agencies.

24 Q. Okay. Which were the police
25 agencies?

1 A. The first one was the Wayne
2 County Sheriff's Department, 1976 to 1981,
3 and I left employment at the Wayne County
4 Sheriff's Department, which would be in
5 Detroit, Michigan, all of Wayne County,
6 that's where we're at today. And then I
7 moved to Romulus Police Department, which is
8 Romulus, Michigan. That's the community
9 where probably most everyone flew in. It's
10 around the Detroit Metropolitan Airport.

11 Q. Okay. So 27 years as a police
12 officer, right?

13 A. Yes, sir.

14 Q. Okay. And then you joined the
15 DEA; is that correct?

16 A. At some point. I retired in
17 2002. I did not join the DEA until 2004.

18 Q. What happened in those two
19 years? Just retirement?

20 A. No, I kind of had an aspiration
21 to be a teacher, so I started to do some
22 teaching. I got a vocational certification,
23 and I was a teacher with -- I did some
24 substitute teaching and some baseball
25 coaching with the Romulus school district,

1 and then I did vocational certification with
2 the Livonia Public Schools and I taught there
3 for one year before leaving for the DEA.

4 Q. What did you teach?

5 A. I was called a shared time
6 teacher. So in Michigan, property owners pay
7 property taxes which fund the public schools,
8 while private schools are tuition based. So
9 there was some kind of decision, and I don't
10 know the law or the legality of it, but -- I
11 shouldn't say legality, but what caused it.

12 So then public school teachers
13 would go into private schools and instruct
14 private students, mostly religious schools,
15 faith-based schools. So I taught computers,
16 some mathematics and some physical education.

17 Q. Okay. And after a couple of
18 years of that, you joined the DEA; is that
19 correct?

20 A. Yes, sir.

21 Q. And you were with the DEA from
22 when to when?

23 A. 2014 until June 2017.

24 Q. 2014 or 2004?

25 A. 2004.

1 Q. Okay.

2 A. Sorry.

3 Q. It's okay. 2004 to 2017.

4 Now, during the time that you
5 were at the DEA, what was your position?

6 A. Diversion investigator.

7 Q. Okay. Did that job ever
8 change?

9 A. My title, no, sir.

10 Q. Your title, yeah.

11 A. No, sir.

12 Q. Okay. And in 2017, did you
13 retire, full-time retire or what?

14 A. Yes, sir, that was my
15 intention.

16 Q. Okay. But then you got this
17 thing?

18 A. Yes, sir.

19 Q. Okay. Now, just so I know a
20 few more things, you are not -- let me start
21 again.

22 Have you ever been certified as
23 an expert witness in a case before?

24 A. I have not been certified
25 before, no, sir.

1 Q. Have you ever served as an
2 expert witness on a consulting basis before?

3 A. No, sir, I have never served as
4 an expert in the capacity of a consultant.

5 Q. Okay. Have you ever written
6 any articles that were published?

7 A. No, sir.

8 Q. Have you ever written anything
9 of any kind that was published?

10 A. As a police officer, I wrote an
11 article at the request of the Detroit News.
12 It was in regards to the effectiveness of the
13 DARE program.

14 Q. Okay. So you wrote something
15 for the Detroit -- is it the Detroit News?

16 A. Detroit News, it's the
17 publication.

18 Q. Did that used to be the Detroit
19 Free Press or is that a different paper?

20 A. Different paper. Still two
21 papers in Detroit.

22 Q. Okay. Was that like an op-ed,
23 like an editorial kind of thing?

24 A. Sure. They published two, I
25 guess, opinions, a pro and a con opinion.

1 Mine was the pro opinion of DARE, and there
2 was a side-by-side con opinion of the
3 effectiveness of that program.

4 Q. Okay. So you wrote that. Is
5 there anything else you've ever written
6 that's been published?

7 A. Not that I'm aware of, not that
8 I gave any authorization for, no, sir.

9 Q. Okay. Have you -- and this is
10 pretty obvious, but you're not an attorney;
11 is that correct?

12 A. Not an attorney, no, sir.

13 Q. So in giving your opinions
14 today, you're not trying to give legal
15 opinions; is that right?

16 A. Well, the opinion I'm trying to
17 give is based on my training and experience
18 and my knowledge of the law and the
19 regulations that are required to be adhered
20 to by the companies. I'm not publishing a
21 legal opinion as an attorney.

22 Q. Well, what I'm asking you is
23 whether you -- are you offering today or in
24 your report a legal -- a legal conclusion?

25 A. I think, yes, I am.

1 Q. Okay. Let me ask you a little
2 about the work you've done in connection with
3 this report.

4 First of all, the report is 180
5 pages, I believe.

6 A. It is, sir.

7 Q. Did you write it?

8 A. Yes, sir.

9 Q. Okay. You wrote it yourself or
10 did you write it with help?

11 A. I wrote it with help.

12 Q. Okay. How much time did you
13 spend preparing your report?

14 A. Well, I didn't keep track if
15 you're going to ask me the exact hours, but I
16 would say a considerable amount of time. It
17 pretty much consumed me.

18 Q. When did you start working on
19 the report?

20 A. Well, probably in the fall of
21 2018, I started having discussions about the
22 type of documents and records that I would
23 need, some of the topics in potential
24 depositions, questions I would need to
25 answer. So I started to give the framework

1 and the guidelines of what information would
2 be required. It was around that time when I
3 had a pretty clear understanding of what I
4 would give an opinion on.

5 When I first started I was more
6 of a consultant than an expert witness, so,
7 you know, I wasn't exactly sure what I was
8 going to be asked to give an expert opinion
9 on.

10 Q. So until the fall of 2018, is
11 it correct that you were working as a
12 consultant for the plaintiffs in this case?

13 A. Well --

14 Q. Starting in 2017.

15 A. -- I guess that would be my
16 capacity. I didn't do any testifying, so I
17 guess I wouldn't be considered an expert
18 witness. I don't know that there was a
19 capacity at that time, so I think that's a
20 fair statement.

21 Q. But did you work -- did you put
22 work into this case from the time you were
23 retained in 2017 up until 2018 when you
24 started working on the report?

25 A. I would say yes, but it would

1 be a different kind of work because obviously
2 when the discovery came in and the records
3 were available and the depositions began,
4 then there was a different kind of
5 information. But there was always a little
6 bit of a process because I knew at some point
7 I was going to be potentially asked to
8 publish an opinion.

9 Q. Okay. Do you know how many
10 hours you spent or how many days or how many
11 weeks you spent working on the case
12 from two-thousand-and -- let's say from the
13 time you were retained in 2017 until the fall
14 of 2018?

15 A. Somewhere a little below or
16 above 400 hours.

17 Q. Okay. And that takes you up to
18 the fall of 2018, right?

19 A. That takes me today.

20 Q. I see. So you spent about
21 400 hours from the beginning of being
22 retained until today working on this matter?

23 A. Yes, sir.

24 Q. Okay.

25 A. I'd like to add that I'm

1 probably not as diligent on my billing as I
2 should be. I know some people might bill for
3 every minute. I don't do that, so -- but
4 that would be an accurate amount of time that
5 I -- at least that I submitted for billing.

6 Q. Okay.

7 A. I probably spent more than
8 400 hours on the project.

9 Q. So do you know how much in
10 terms of dollars you have submitted for
11 billing?

12 A. Well, 101,000 and a little over
13 that.

14 Q. Okay. Tell me how you made --
15 tell me how you obtained the materials you
16 needed to prepare your report?

17 A. Both in -- mostly in verbal
18 requests and discussions. I think there were
19 some -- I crafted some e-mails, which had
20 specific types of documents that I would need
21 and submitted them to the attorneys. That
22 started a discussion on the types of
23 documents I'd need to review.

24 Q. Okay. And how did -- if you
25 don't mind my asking, how did you know what

1 to ask for? There are millions of documents
2 in this case and many, many depositions. How
3 did you know what to request?

4 A. Based on my experience in
5 conducting similar type of investigations of
6 both distributors and manufacturers, I had a
7 pretty good idea of the type of records and
8 documents or questions I would need answered
9 to formulate an opinion.

10 Certainly there were things
11 that -- documents that were submitted or
12 deposition answers or questions that I hadn't
13 thought of, but they also became available to
14 me.

15 Q. How did they become available
16 to you?

17 A. Well, in drafting my report,
18 there would be certain topics regarding the
19 maintenance of effective controls, suspicious
20 order systems. People would also assist me
21 in reviewing the documents and they would
22 find articles or statements or policies that
23 would be brought forward to my attention,
24 sometimes with a written explanation or draft
25 explanation, and I'd review those and

1 either -- not dismiss them, but review them
2 and either incorporate them or not
3 incorporate them in my report.

4 Q. When you say people would
5 review things and send them to you, are you
6 talking about the plaintiffs' attorneys?

7 A. Yes, sir.

8 Q. Okay.

9 A. Only the -- well, let me
10 correct that.

11 My communications would flow
12 through just a couple of specific attorneys,
13 and they would come back from them. So I
14 don't know if they were attorneys or legal
15 aides or -- I don't know exactly who would
16 draft some of the information I would review.

17 Q. What were the name -- who were
18 you dealing with?

19 A. Mr. Fuller, Mr. Elkins, and for
20 a period of time a Laura Baughman. I think
21 she left her law firm. So those were
22 primarily the three people.

23 Q. Okay. Did you have anyone else
24 assisting you with this report?

25 A. No, sir.

1 Q. Who typed the report?

2 A. I typed it.

3 Q. Now, you said that they
4 would -- that Mr. Fuller and Ms. Baughman and
5 Mister -- I'm sorry --

6 A. Elkins.

7 Q. -- Elkins, who I guess is
8 sitting next to Mr. Fuller?

9 A. He is.

10 MR. NICHOLAS: Hello,
11 Mr. Elkins.

12 MR: ELKINS: Good morning.

13 BY MR. NICHOLAS:

14 Q. Would send you drafts of things
15 and you would review them. What do you mean?
16 Did they send you drafts of portions of the
17 report?

18 A. Sure. There may be a section
19 of the report, maybe a policy, or there may
20 be some specific documents that they would
21 give an evaluation of or at least describe
22 it, and I would review it and make edits,
23 corrections, deletions and either incorporate
24 it into my report or not incorporate it in my
25 report.

1 Q. And is it fair to say that
2 that's how the report was written, that the
3 plaintiffs' lawyers sent you draft sections,
4 you would review them and revise them as you
5 saw fit, and that is how the report came to
6 be?

7 A. I wouldn't say that's an
8 accurate statement. I mean, I wrote the
9 report, it's my report. I put pen to paper.
10 There may be sections in here that I
11 incorporated, but every section would have
12 been edited, drafted, corrected or reviewed
13 by me.

14 Q. Right.

15 A. So there's no sections in here
16 that I just plugged in that someone else
17 wrote. It's all my work product.

18 Q. Which -- roughly, okay? Can
19 you tell me how -- what percentage of this
20 report started with a first draft from the
21 plaintiffs versus a first draft from you?

22 A. I'm not really sure how to
23 answer that. Are you looking for like a
24 percent or --

25 Q. I don't know. Number of pages.

1 You know, how much of this 180-page report,
2 how many pages -- for how many pages did you
3 write the first draft and how many pages did
4 the plaintiffs write the first draft?

5 A. Well, I'm unsure of how to give
6 you a number, because I really didn't -- it
7 wasn't a kind of draft where I knew exactly
8 how many pages the first time. It was
9 substantial at the beginning, I would say
10 around the 100-page mark, and then as more
11 records were found, more documents, as the
12 report was written, one section would trigger
13 an analysis that would lead to another
14 section and it would probably be a lot
15 thicker if I would have had the ability to
16 work around the clock and stay up all night
17 because it's -- you know, it's a complex
18 matter.

19 There's numerous companies,
20 millions and millions of documents. I by no
21 means am trying to represent to you or the
22 court that I've read every document in
23 regards to the discovery because I don't
24 think that's physically possible.

25 Q. Do you know whether you --

1 well, so you have not reviewed all the
2 documents that have been produced in
3 discovery, right?

4 A. No, that would be impossible.

5 Q. Right. Do you know whether
6 you've reviewed the most important documents
7 in the case?

8 A. I believe I have with the
9 assistance I was provided, being I gave the
10 guidelines of the type of documents I wanted
11 to be provided or reviewed. And I'm -- I'm
12 fairly confident -- I'm very confident that
13 I've got enough information to make this
14 opinion, and I'm sure that if I've missed
15 some documents, I'm going to hear about it in
16 the next two days.

17 Q. Who -- who made -- who sent you
18 the documents? The plaintiffs' lawyers?

19 A. Yes.

20 Q. Okay.

21 A. Primarily Mr. Elkins.

22 Q. Okay. So, for example, if
23 there were -- I don't know how many
24 depositions have been taken in the case, but
25 there have been many, many depositions.

1 How did you know -- how did you
2 know which ones to ask for, which transcripts
3 to ask for?

4 A. Well, at the beginning I
5 started to read them, and I realized that it
6 was impossible for me to read and take notes,
7 so I read a couple at the beginning which, by
8 probably more luck than anything because they
9 just started to come to me in writing, not
10 electronic, I read some depositions that were
11 key to the discovery -- I mean key to the
12 investigation.

13 At a later point, attorneys
14 obviously would know based on the type of
15 questions I wanted answered and the positions
16 of the people who were being deposed that
17 some depositions were more crucial than
18 others.

19 Q. So the attorneys made the
20 decisions as to which of the depositions you
21 should review, right?

22 A. I don't know if they made the
23 decisions. I think they pointed me to
24 depositions where they thought there was
25 content that would be important to me, and I

1 would review those sections of those
2 depositions.

3 Q. Okay. So just by way of
4 example, do you know who Kyle Wright is?

5 A. I am -- I do. Yes, sir.

6 Q. Okay. Did you read his
7 deposition?

8 A. I believe I read a portion of
9 it. I didn't read the entire deposition.

10 Q. Because I don't think your
11 report reflects that you've reviewed his
12 deposition. That's why I'm asking.

13 A. I'm not sure that he had any
14 information in his deposition I would have
15 used, but I did review -- I didn't review his
16 entire deposition, but I do recall that I did
17 review some of it, yes, sir.

18 Q. If you reviewed his deposition,
19 is there a particular reason why you didn't
20 say in your report that you reviewed his
21 deposition? Was it just an oversight?

22 A. I don't know that I would be
23 required to put that in my expert report,
24 whether or not -- I reviewed a lot of
25 depositions and not all of them are --

1 there's no notation that that occurred in
2 this report.

3 Q. Well, I think we need to know
4 everything you reviewed in order to be able
5 to ask you questions about your report, so if
6 there are -- are you saying there are things
7 that you reviewed in connection with this
8 report that you didn't identify as having
9 reviewed? Kyle Wright's deposition is one
10 example. Are there others?

11 A. Well, recently I reviewed a
12 portion of Thomas Prevoznik's deposition.
13 I'm sure there are some other depositions
14 that I reviewed that aren't cited in my
15 report. Possibly those individuals didn't
16 have any information that would have provided
17 me with any guidance in my opinion.

18 For example, I recall reading
19 one on a sales personnel. Might have been
20 from AmerisourceBergen or Cardinal, and
21 really, there was nothing relative to that
22 that would help me make my expert opinion in
23 regards to the conduct of that company.

24 Q. So you didn't identify that in
25 your report as something you read?

1 A. No, sir. I did prepare a list
2 of documents that I utilized and provided it
3 to the attorneys at their request.

4 Q. Okay. So there are documents
5 that you reviewed for this report, and right
6 now we don't know what they are because you
7 haven't identified them. That's all I want
8 to know.

9 A. That's a true statement. There
10 were probably some depositions that I took or
11 some records -- not every record I looked at
12 is documented in this report. There's
13 multiple, multiple depositions. There's
14 5 million documents. I was never instructed
15 as a witness that I had to keep a laundry
16 list of everything I looked at or everything
17 I reviewed.

18 Q. Did you find anything in
19 your --

20 MR. FULLER: Form to the last
21 question.

22 MR. NICHOLAS: Say again.

23 MR. FULLER: Form to the last
24 question. Counsel, you stated that --

25 MR. NICHOLAS: It's okay. You

1 made your objection.

2 MR. FULLER: No. You stated
3 that there are documents in here that
4 he reviewed related to his report. I
5 think the testimony is that he
6 reviewed documents but they didn't
7 impact his report.

8 MR. NICHOLAS: They didn't
9 impact your report.

10 BY MR. NICHOLAS:

11 Q. In your review of all of these
12 documents and all these depositions that you
13 read, did you find anything in any of them
14 that was in any way favorable to any of the
15 defendants in the case?

16 A. There were a couple of things
17 that I thought were -- I wouldn't say
18 favorable. That I thought were a positive
19 measure by the companies.

20 Q. Did you reference those in your
21 report?

22 A. Both of the things that I'm
23 thinking of happened right at -- the timeline
24 would have been right near the end of the
25 2013 -- or, I mean, sorry, one was right

1 before 2017, and the other one was with a
2 company and right about when they were making
3 those changes, they gave up their authority
4 or their distribution of controlled
5 substances, so I did not make comment on
6 that. It didn't impact their conduct during
7 the timeline of my report.

8 Q. That's one. What was the other
9 one?

10 A. Well, there's two. One was
11 right near the end of -- in 2017, they were
12 making some changes to their suspicious order
13 monitoring system that I thought were pretty
14 positive and significant, but it was right at
15 the very end of the timeline. That was one
16 company. That would have been McKesson.

17 And then CVS made some changes
18 right near the end of the time they handled
19 controlled substances. I think it was around
20 2000 -- I don't want to say a date. I want
21 to check my report. I don't want to be
22 inaccurate. But at some point they just gave
23 up distributing controlled substances, and it
24 was right near that time period.

25 Q. Are these two facts in your --

1 A. No, sir.

2 Q. You didn't put those in your
3 report?

4 A. No, sir.

5 Q. Other than those two things, is
6 there anything that you reviewed in all of
7 the documents that was in any way positive or
8 favorable to any of these 12 defendants?

9 A. I would have to say, sir, in
10 looking at all the records, in the records
11 that I asked for -- and I'm going to restate,
12 I didn't read all 5 or 6 million documents
13 that were provided. The documents that I
14 reviewed or that were provided to me, I would
15 have to say no.

16 There was -- I was actually
17 somewhat shocked by the level of failure in
18 the documents that I reviewed, by the
19 companies.

20 Q. The documents that were sent to
21 you by the plaintiffs' lawyers?

22 A. And that I elected to review
23 based on what they were, policies,
24 procedures, descriptions of systems,
25 particular depositions where people that had

1 knowledge how the system would work or
2 whether it was utilized.

3 So it wasn't just -- just so
4 I'm clear, I wasn't being spoon-fed just
5 particular documents. I just want to make it
6 clear to the court and to the judge that I
7 couldn't physically look at every document.

8 Q. How many documents did you
9 review, do you know?

10 A. Well, no, I have no idea.
11 Extensive.

12 Q. Okay. Did you speak with
13 plaintiffs' lawyers in connection with
14 drafting this report?

15 A. Could you explain that
16 question?

17 Q. Did you talk to Mr. Fuller or
18 Mr. Elkins or Ms. Baughman about the content
19 of the report?

20 A. I think there was some general
21 conversation, just -- just not what to write,
22 but I've never written an expert opinion,
23 report before, so obviously I needed a little
24 bit of guidance on how it would flow. So how
25 it's laid out, the beginning with my

1 experience, somehow how it's divided by
2 company. I mean, some of the general
3 formatting, you know, that I had to come to
4 some conclusions.

5 I was told what topics that I
6 would be expected to give an opinion on. I
7 was also told to stay within the guidelines
8 of those opinions, not to, you know, get into
9 topics that were outside of that, those -- my
10 opinions.

11 Q. And what topics were you told
12 to give an opinion on?

13 A. Maintenance of effective
14 controls to prevent diversion, which is both
15 in the law and federal regulations, and
16 suspicious -- designing and operating a
17 suspicious order system, CFR 1301.74(b).

18 Q. Did you ever meet with any of
19 the other experts in the case?

20 A. I have.

21 Q. That are -- let me start again.

22 Did you ever meet with any of
23 the other experts in the case who were
24 working with the plaintiffs?

25 A. Yes, sir.

1 Q. Okay. Who did you meet with?

2 A. Physically I had a meeting with
3 Mr. McCann in Arlington on two different
4 occasions.

5 Q. Okay.

6 A. By telephone, there was an
7 expert witness, and I hopefully have his name
8 correct. I think it was Seth Whitehill or
9 Whitehall.

10 Q. Uh-huh.

11 A. And then there was another
12 expert opinion and -- I was anticipating this
13 question, I was trying to remember. I
14 believe -- I only remember her first name. I
15 think it was Hui, but I don't -- I'm sorry --
16 I don't -- you know, I have a recollection --

17 Q. That was a phone call or a
18 meeting?

19 A. That was a phone conversation.
20 One phone conversation with her. I had two
21 phone conversations with Mister -- Seth. I
22 remember his first name. It was either
23 Whitehill or Whitehall.

24 Q. And two in-person meetings with
25 Mr. McCann? One?

1 A. Well, I don't know so much that
2 I would call them meetings.

3 Q. What would you call them?

4 A. Well, the first one is we went
5 to his company in -- me and some other
6 people, and that's when they had received the
7 ARCOS data, and it came in in a native
8 format, just as a string of numbers, EDI
9 format. I think they were maybe anticipating
10 it was going to come in in a different, more
11 readable style.

12 So I met with them just to kind
13 of give them some guidance on what the ARCOS
14 materials should look like. Would you like
15 an example?

16 Q. Not right now. Let me ask
17 you --

18 A. And then the second meeting?

19 Q. Yeah.

20 A. The second meeting was right
21 after Christmas. There was some kind of a
22 work product that Mr. McCann did, and it went
23 out to some groups of people, and I was asked
24 to go to his office and sit in the
25 conversation room in case I received any

1 calls from plaintiff attorneys that had
2 questions about the data that they had
3 received. And I received no calls, so it
4 was just -- sat in a room, had a casual
5 conversation with Mr. McCann, but it wasn't
6 in regards to any of the analysis or any of
7 the work.

8 Q. Okay. I need to -- I think I
9 need to understand this just a little better.

10 A. Sure.

11 Q. So the first meeting with
12 Mr. McCann had to do with the ARCOS data and
13 making it sort of more understandable?

14 A. Yes.

15 Q. Right?

16 A. So -- yep.

17 Q. Okay.

18 A. So you want an explanation of
19 it?

20 Q. No.

21 A. Okay.

22 Q. I guess what I want to know is:
23 Was anyone else there?

24 A. Yes.

25 Q. Who else was there?

1 A. There was a couple other
2 experts -- well, I guess consultants, former
3 DEA employees were there present, and also
4 there was one attorney, one plaintiffs'
5 attorney.

6 Q. Who were the other consultants?

7 A. James Geldhof. I'm trying to
8 think who was all there. Frank Younkers, and
9 I think there may have been one more. I'm
10 not sure. And one attorney.

11 Q. Who was the attorney?

12 A. Peter Mougey.

13 Q. How long was that meeting?

14 A. Well, I wouldn't really
15 consider it a meeting. It was kind of a --

16 Q. Were you in a room together?

17 A. Yes.

18 Q. Okay.

19 A. So it wasn't like a formal
20 meeting where we had discussions. There was
21 just basically some back-and-forth on trying
22 to understand how to get the ARCOS into a
23 usable format.

24 Q. Whether you call it a meeting
25 or all sitting in a room together and

1 talking, how long was it?

2 A. Oh. It was the better part of
3 a day. The first day, six or seven hours.
4 The second day it was a partial part of the
5 day.

6 Q. Okay. So it was a meeting that
7 occurred over two days?

8 A. Yeah.

9 Q. And that was in Arlington,
10 Virginia?

11 A. Yes, sir.

12 Q. All right. Had you ever met
13 any of those guys before?

14 A. I had. Well, I had not met
15 Mr. McCann before.

16 Q. Okay.

17 A. But I had met Mr. Frank
18 Younkers and James Geldhof. There was
19 another expert, and his -- I remember his
20 name. David Schiller. I had never met him
21 prior to that day. He was a former DEA
22 employee also.

23 Q. And Younkers and Geldhof you
24 knew from what, DEA days?

25 A. Yes.

1 Q. Okay. I don't want to get into
2 a big thing about it, but where did they --
3 how did you know -- how did you know them
4 from DEA days? What did they do?

5 A. Mr. Geldhof, he was the
6 diversion program manager.

7 Q. Where?

8 A. Let me back up.

9 Q. Yeah.

10 A. When I first started, he was my
11 immediate supervisor for a short period of
12 time, and then he was promoted, so he was in
13 the Detroit division office as the diversion
14 program manager, which would be one level
15 above my supervisor.

16 Frank Younkers was the group
17 supervisor in the Cincinnati DEA office,
18 Cincinnati, Ohio. I did some cases in
19 Cincinnati and I met him just as an
20 introduction and say hi. I never really
21 worked with him or had any supervision by
22 him.

23 Q. Okay. But Mr. McCann and
24 Mr. Whitehall and the woman that you
25 referenced are all people you'd never met

1 before?

2 A. That's correct.

3 Q. You were introduced by the
4 plaintiffs' attorneys basically?

5 A. Yes, sir.

6 Q. Okay. And the phone call with
7 Mr. Whitehall was about what?

8 A. Well, my expert opinion has to
9 deal with the companies' actions and
10 compliance with regulations and the law, and
11 my -- I guess my understanding of what
12 Mr. Whitehill does is he looks at the
13 companies for more of a larger corporate type
14 of compliance, maybe how the companies set up
15 their compliance in more of a big, broader
16 overview.

17 I really didn't see any
18 connection between what his opinion was going
19 to be and my opinion, but at the request of
20 plaintiff counsels, we had a couple of
21 discussions.

22 Q. So you talked more than once?

23 A. Yes, sir.

24 Q. On the phone?

25 A. Yes, sir.

1 Q. Were lawyers on the phone with
2 you when you talked?

3 A. Yes, sir.

4 Q. Who were they?

5 A. Well, for sure I knew Amy
6 Quezon was on the phone. She's the one who
7 arranged the phone conferences. I believe
8 Mr. Fuller might have been. I'm not sure. I
9 think he might have been off and on. And
10 it's possible Mr. Elkins. It wasn't the kind
11 of a formal meeting where everyone announced
12 themselves. There was an introduction
13 between me and Mr. Whitehill, and I think
14 Amy, Ms. Quezon, helped with the
15 introduction.

16 So it wasn't where I took a
17 roll call or notes, so I'm not sure, but I
18 believe those people at some point might have
19 been on the conversation.

20 Q. Were you ever on --

21 I'm sorry, I didn't mean to
22 interrupt.

23 A. No, that's okay.

24 Q. Were you ever on the phone with
25 any of the other experts in the case or in a

1 meeting with any of the other experts in the
2 case where there weren't also at least one
3 plaintiffs' lawyer there?

4 A. So, I know you -- we aren't
5 agreeing on the term "meeting." There were
6 some periods of time where I was reviewing
7 depositions and James Geldhof was also tasked
8 with doing -- reading depositions.

9 So we would review depositions
10 and then once a week we would meet and we
11 would compare our review of those
12 depositions. And at the conclusion we put a
13 product together to send to the attorneys. I
14 would put a product together.

15 Q. So you were working with
16 Mr. Geldhof on your report?

17 A. It wasn't on my report at that
18 time. I hadn't really started writing my
19 report because the discovery material,
20 really, wasn't available -- I don't know if
21 it was in, but it wasn't available to me.
22 But the depositions were underway. And
23 actually, I wasn't even aware they were
24 underway.

25 I remember receiving a phone

1 call and kind of asked what I was doing, and
2 I said nothing. I hadn't heard from the
3 plaintiffs in a couple of months during the
4 summer months, which I wasn't complaining
5 about because I was enjoying my summer. And
6 then they said they wanted to start sending
7 depositions and for me to review them. So
8 then boxes started to arrive at my house.

9 I immediately knew that I would
10 never be able to read all of the depositions,
11 so I started with one particular company and
12 started reviewing those depositions.

13 Mr. Geldhof had already -- he
14 was a lot more diligent than me in reading
15 the depositions. So the ones that we both
16 read, it wasn't like a concerted effort; we
17 would just meet and discuss our review of the
18 depositions.

19 Q. All I'm really trying to
20 understand is whether, for your report, you
21 had anyone else working with you or for you,
22 whether it's Mr. Geldhof or anyone else?

23 A. No, sir. No, sir. The only
24 person I had those discussions with was
25 Mr. Geldhof. Now, he may have seen something

1 in a deposition that I missed or didn't bring
2 to my attention, so I would go back, take
3 some notes, review the deposition myself, and
4 either find that it was useful and
5 incorporate it, or dismiss it.

6 Q. In connection with putting
7 together your report, did you speak with
8 anyone or interview anyone from Summit or
9 Cuyahoga County?

10 A. No, sir.

11 Q. Did you visit any pharmacies in
12 Cuyahoga or Summit County in connection with
13 putting your report together?

14 A. No, sir, I did not visit any
15 pharmacies.

16 Q. Okay. Did you spend any time
17 in Cuyahoga or Summit County at all in
18 connection with putting together your report?

19 A. Well, in a broad sense I'd have
20 to answer yes, and that's because I attended
21 some of the court hearings at the request of
22 the plaintiffs' attorneys, so I was able to
23 hear some of the presentations that were
24 made, which I guess would be useful in some
25 ways of guiding me.

1 I wasn't -- I don't think I was
2 requested to be there for that particular
3 purpose to use that information, but I think
4 any information that I received in regards to
5 this report and -- I keep calling it
6 investigation -- my evaluation, was impactful
7 in crafting my report.

8 Q. Which -- do you remember which
9 court hearings you went to?

10 A. I went to the one, and I don't
11 remember the date, I'm sorry, where
12 Mr. Rannazzisi testified, and there was a
13 document presented on behalf of the DEA. I
14 think it was -- it was a large hearing. I
15 know that.

16 Q. I remember it.

17 A. Okay. I was there.

18 Q. I was there, too.

19 A. Only because they made me sit
20 up at the very front, which I wasn't very
21 comfortable with.

22 Q. Well, get used to it. You may
23 have to testify in the case, you know.

24 A. Well, I know. I understand
25 that, but when everyone's in the courtroom

1 and you're told to sit up here in the front,
2 kind of in front of the jury box, I was a
3 little nervous up there.

4 Q. And did you go to any other
5 hearings?

6 A. No, sir.

7 Q. Okay. So did you review any of
8 the deposition transcripts of any of the
9 Summit or Cuyahoga County officials?

10 A. No, sir.

11 Q. Okay. Did you ask for them?

12 A. No, sir.

13 Q. Did the plaintiffs' lawyers
14 send them to you?

15 A. I have numerous boxes of
16 depositions at my house that I haven't went
17 through them all, so I can't answer one way
18 or another if one of them may be in there.
19 So I have to say I don't know.

20 Q. Do you know who Demetra Ashley
21 is?

22 A. I do.

23 Q. Did you overlap with her at all
24 in Detroit? Because she worked in Detroit as
25 well.

1 A. So during -- we hadn't
2 discussed this, but during my career as a
3 Romulus police officer, I was actually a
4 sergeant, I was head of a narcotics unit for
5 the city police department. So in the course
6 of some narcotic investigations, I got an
7 invitation from the DEA to become a task
8 force officer.

9 So I left my department for a
10 period of about -- almost five years and
11 worked in the capacity that would be similar
12 to an agent, which is different than a
13 diversion investigator.

14 I believe she was there then.
15 I'm pretty sure she was there then, so if I
16 met her, it was just casually.

17 My only recollection -- to be
18 honest with you, I didn't know that diversion
19 even existed in my law enforcement career,
20 and -- not that I want to digress, but they
21 would destroy drugs once a month, so I'd come
22 to work and everybody would be in the hallway
23 just getting rid of cough syrup and there
24 would be this awful smell. And it would be
25 like kind of a joke that day, on drug

1 destruction day. And I'm sure that I met her
2 in that time period.

3 Q. Okay. And are you aware that
4 there came a time in 2015 when she actually
5 moved into one of the top positions at the
6 DEA?

7 A. Yes, sir.

8 Q. In fact, she and Mr. Milione
9 kind of replaced Mr. Rannazzisi. You knew
10 that, right?

11 A. Yeah, so -- and I don't know if
12 this would be something that your question --
13 that I should have answered previously. She
14 was in her capacity near the end of my career
15 where one of my cases, there was
16 negotiations, and she -- or discussions about
17 the case, and she was part of those
18 discussions.

19 Q. Okay. You did not -- your
20 report doesn't say that you reviewed her
21 deposition either. Did you review her
22 deposition?

23 A. I started to review it, but I
24 would probably say maybe the first 20 pages.

25 Q. Just 20 pages?

1 A. I think so.

2 Q. Okay.

3 A. Maybe a few more, but I did not
4 read the full deposition.

5 Q. Okay. Thank you for all that.

6 A. Yep, you're welcome, sir.

7 Q. I apologize for taking so much
8 time on this background stuff, but someone's
9 got to do it.

10 A. I understand.

11 Q. Are you familiar with the
12 regulation that discusses suspicious orders,
13 regulation 1301.74, subpart (b)?

14 A. Yes, sir.

15 Q. All right. And does that
16 regulation define suspicious orders?

17 A. I think the regulation itself
18 is a broad regulation and, I think, for a
19 good purpose. I think it gives some guidance
20 on a suspicious order, but I think the actual
21 full definition is up to the registrant,
22 depending on a lot of factors; the scope of
23 their business and the scope of those
24 customers that receive products from them.

25 So I think -- I know there's a

1 lot of criticism about the -- or there's some
2 criticism about the regulation. I think it's
3 a perfect regulation for industry to adhere a
4 specific program to.

5 Q. The regulation defines
6 suspicious orders as orders of unusual size,
7 orders deviating substantially from a normal
8 pattern, and orders of unusual frequency; is
9 that correct?

10 A. Well, that is what the
11 regulation says, but -- but I'm not so sure I
12 agree if you're saying the word "defines"
13 says that suspicious orders could only be
14 those things.

15 I think that's up to the
16 registrant to -- because there could be other
17 factors where a suspicious order could be
18 identified other than those three parameters.

19 Q. Does the order tell the
20 registrant what is meant by an order of
21 unusual size?

22 MR. FULLER: Form.

23 A. No, I think that's up for the
24 registrant to define based on their
25 application of their maintenance of effective

1 controls. You know, that question has come
2 up before. I think the important thing first
3 for a company or a registrant is define what
4 "usual" is, and that would be their due
5 diligence and their maintenance of effective
6 controls.

7 Many companies focus on trying
8 to define an unusual order when they don't
9 sufficiently understand what a usual order is
10 in regards to what kind of business they're
11 operating and the scope of their business.

12 MR. FULLER: Bob, and not to
13 pick on your flow, but your last
14 question was does the order tell the
15 registrant.

16 MR. NICHOLAS: Oh, my mistake.

17 MR. FULLER: That's why I
18 objected.

19 MR. NICHOLAS: I appreciate it.
20 Well, then I appreciate it.

21 MR. FULLER: But Rafalski still
22 answered it.

23 MR. NICHOLAS: That's fine.

24 THE WITNESS: I thought I had
25 to.

1 MR. FULLER: No, but he asked
2 does the order tell the registrant.

3 THE WITNESS: I'm sorry.

4 MR. FULLER: But you meant the
5 regulation.

6 MR. NICHOLAS: Yeah.

7 MR. FULLER: Fair enough.

8 THE WITNESS: So is my answer
9 correct? I mean, not correct. Was it
10 on point? I'll take it back.

11 MR. NICHOLAS: We're going to
12 sync up your answer with my screwed-up
13 question with the correction, and it's
14 going to work.

15 THE WITNESS: Sorry.

16 BY MR. NICHOLAS:

17 Q. So is it fair to say that the
18 determination as to whether an order is of
19 unusual size is a subjective determination?

20 A. No, I don't think so.
21 Generally speaking, I think if --
22 hypothetically, I think that if a company,
23 especially a large company, has sufficient --
24 sufficient data that they can come up with a
25 reasonable, usual amount that a customer

1 would be expected to purchase, and I think
2 that a purchase that would exceed that as a
3 system that would trigger that order to be of
4 unusual size, I don't think that's a
5 subjective nature.

6 Certainly, I guess companies
7 could just hire people to just look at orders
8 and then say that's an unusual order and that
9 would be more of a subjective, but I think
10 any system that's designed takes the
11 subjective nature out of it.

12 Now, subsequent decisions may
13 be subjective, but the actual identification
14 would not be.

15 Q. What do you mean by "subsequent
16 decisions"?

17 A. So an order is -- triggers as
18 unusual order based on the size, and then the
19 company has a couple of decisions to make.
20 One, and this is based on my experience and
21 based on the Masters case, is they could
22 report it to the DEA and then not ship it and
23 that could be the end of it.

24 So if they want to make a
25 determination on whether or not they want to

1 ship it, they have to dispel the fact that
2 it's a suspicious order to make sure that
3 it's not diverted.

4 So someone obviously would have
5 to gather some facts, and I guess make an
6 evaluation of those facts. So what facts
7 that that person, he or she, gathers and
8 their opinion on whether or not it's
9 suspicious, I think there has to be some
10 level of subjectivity in there.

11 You could have a checklist and
12 you could have a lot of formal procedures,
13 but ultimately, someone has to make some
14 decision.

15 Q. I would ask you the same
16 question about orders that deviate
17 substantially from a normal pattern. Is the
18 determination of whether orders deviate
19 substantially from a normal pattern a
20 subjective determination?

21 A. My answer is kind of going to
22 run parallel to the size. I think an unusual
23 pattern start -- you know, first a company
24 has to establish what's a usual pattern.

25 In regards to the preparation

1 of my report and review of the policies, one
2 of the most common patterns -- well, I
3 wouldn't say common, but one pattern that
4 some companies elect to look at are the
5 relationship between the purchase of controls
6 and noncontrols.

7 So they can establish with
8 their own records what would be a normal
9 range of noncontrols related to controls. So
10 any change in the purchasing of that would be
11 an example of an unusual pattern.

12 Another one that some companies
13 in my preparation of my report would be cash
14 payments versus insurance payments, so that a
15 change in the percentage there. That would,
16 of course, only occur if the companies were
17 diligent, asked that question on a periodic
18 basis.

19 There are many other patterns
20 that are overlooked in my preparation of the
21 report by companies. One of the easiest
22 would be companies generally seem to be
23 looking at drugs as families, and what I mean
24 by that is lumping all the oxycodone products
25 into one family or by their drug code.

1 So within those families,
2 there's -- my experience in doing these cases
3 is there's generally a hierarchy of drugs
4 where some drugs are ordered more often than
5 others. They're just generally prescribed
6 more.

7 So during the course of when a
8 potential diversion would occur, there could
9 be one strength of drug which actually
10 occurred -- which really impacted what
11 happened in America -- the oxycodone 30
12 product became a highly abused product. So
13 companies should or would want to monitor
14 within that drug family if there was a change
15 in pattern where one drug started to get
16 ordered in a much greater amount than the
17 other drugs.

18 Along those same lines, another
19 pattern is how companies order drugs.
20 Typically in the old days they used DEA
21 Form 222s. That's a paper form with ten
22 lines. Some companies generally order drugs
23 in the same manner.

24 I've reviewed countless number
25 of forms, and as you go through the forms day

1 by day, you'll see patterns on how drugs are
2 ordered, certain groups together. In the
3 cases I've worked, when that pattern changes,
4 so an easy one would be all of a sudden you
5 see an order form with ten lines and all ten
6 lines have oxycodone 30. If a company would
7 start to change a pattern of orders like
8 that, that would be an easy one.

9 Q. Is it also possible that
10 patterns or size or frequency can change
11 suddenly based on changed circumstances in a
12 particular community?

13 A. Sure, anything is possible.

14 Q. Well, I don't just mean
15 anything is possible. I mean, yes, anything
16 is possible, but I'd like to be a little more
17 specific.

18 A. Okay.

19 Q. Let's say -- let's say a
20 hospital opens up in an area. Would that
21 change patterns and could it change ordering
22 patterns and size of orders and frequency of
23 orders?

24 A. Well, I think that obviously
25 has a possibility to cause some change. I'm

1 not sure that it would change the pattern.
2 It may change the amounts or the types. So
3 another -- as was one of my examples, the
4 types could change.

5 Anytime a business model
6 changes or a new contract -- a better
7 example, if I could give you a better
8 example.

9 Q. Sure.

10 A. Is a pharmacy could enter into
11 a contract with a long-term care facility,
12 and if they didn't provide guidance or
13 information to their distributor, they could
14 just start ordering a controlled substance
15 that would be out of the norm of something
16 they ever ordered before.

17 That's kind of the essence of
18 the suspicious order system because you would
19 hope the system would trigger to stop that
20 order. Then it requires some due diligence
21 where a company would actually call and they
22 would learn about that contract. And then
23 subsequent to that, the distributor or the
24 person making the sale would probably confirm
25 that that actual contract occurred and that

1 business relationship occurred.

2 So...

3 Q. So patterns can change?

4 A. Sure.

5 Q. Size can -- you know, unusual
6 size can change. Frequency can change
7 depending on the circumstances that occur in
8 a particular community, right?

9 A. I've learned in my experience
10 that the ordering and distribution of drugs
11 is not static. It's heavily patterned,
12 especially the more the customers, the more
13 the established pattern, sizes and frequency.
14 But new drugs could be introduced.

15 There's a lot of reasons why it
16 could change. And that's not a bad thing,
17 but those are the things that would trigger
18 your system to stop an order and then you to
19 evaluate it to make sure that -- not you
20 personally, but so that it's evaluated, and
21 then there's no chance of diversion.

22 Q. So while that investigation is
23 going on, you're saying that those drugs
24 should not be shipped to a place where let's
25 say there's a new -- a new long-term facility

1 in town or a pharmacy has a relationship with
2 a new long-term facility? You would stop
3 shipment of those drugs?

4 A. I think that's what the
5 regulation calls for, yes, sir.

6 Q. Okay.

7 A. Well, not the regulation, but
8 the maintenance of effective controls.
9 Because to just go ahead and make shipment
10 without confirming that diversion is
11 occurring, I think the flipside of your
12 question is probably, you know, just as
13 drastic, to allow drugs to go for a purpose
14 when you've already identified that there's
15 the potential for diversion.

16 Q. I mean, it's also drastic if
17 drugs are not going to people who need them,
18 correct?

19 A. That's correct, but in most
20 cases, the drugs we're talking about -- well,
21 let me stop to answer that way.

22 First, the situation would be
23 as I would hope that companies would take
24 into account -- or not that they would have
25 to clear that order in a reasonable amount of

1 time, we're not discussing weeks or months.
2 And I certainly don't speak for the
3 companies, but I'm certain that they act in a
4 fairly quick manner to resolve that. And,
5 you know, I'm not so sure that the drugs
6 we're talking about are -- in a long-term
7 care facility would be life-threatening, but
8 I'm not a doctor, so -- but just generally
9 speaking through my experience.

10 Q. I guess I should have asked you
11 at the beginning. You're not a licensed
12 physician, are you?

13 A. I am not.

14 Q. You're not a pharmacist, right?

15 A. I am not.

16 Q. Okay. But it is correct, isn't
17 it, that the drugs we're talking about,
18 opioids, do serve an important medical
19 purpose, correct?

20 A. Absolutely. I think there's a
21 segment of the population in America that
22 need those drugs.

23 And I think that's an important
24 question and an important answer because, you
25 know, through my career there's a lot of

1 accusations that the DEA works to impede
2 that, and I find that far from the truth. I
3 mean, the number one goal as far as I'm
4 concerned and in our mission statement is to
5 make sure that there's an uninterrupted
6 supply to those people who need those drugs.

7 Q. And sometimes those people need
8 those drugs because they are terminally ill
9 and have a limited amount of time to live and
10 are in tremendous pain in their last days,
11 right?

12 A. There's all --

13 MR. FULLER: Form, scope.

14 MR. NICHOLAS: Go ahead.

15 A. Sure. There's all kinds of
16 reasons why those drugs are a necessity to
17 people that have a medical need for them. I
18 agree.

19 BY MR. NICHOLAS:

20 Q. Okay. I'm going to ask you
21 just a few questions, not many, about three,
22 four pages in your report, pages 10 to 13, in
23 which you discuss something called Discovery
24 Ruling 12.

25 A. Yes, sir.

1 Q. Do you remember that? Do you
2 know what I'm talking about?

3 A. Yes, sir.

4 Q. Okay. And this is a discovery
5 ruling that was issued by Special Master
6 Cohen; is that right?

7 A. Yes, sir, in regards to the
8 Masters Pharmaceuticals case.

9 Q. And you understand that the
10 Special Master's role in the litigation is to
11 address discovery issues, right?

12 A. Generally speaking, yes, sir.

13 Q. Okay. And he is not -- he's
14 great, but he's not the judge, right?

15 A. Understood.

16 Q. Okay. And he's not the jury
17 either.

18 A. Understood. I -- so I think
19 that's one of his roles. I only -- I say
20 that because when I read some of the
21 depositions, I see there's some conversation
22 back and forth about we may have to call
23 Cohen, so I think he maybe makes rulings in
24 regards to deposition matters too.

25 Q. Yeah, and that's part of the

1 discovery process.

2 A. Oh, discovery process, okay.

3 Q. Depositions are part of
4 discovery.

5 A. Understood. Okay.

6 Q. Now, when you discussed his
7 ruling, you put four pages in the report on
8 his ruling. How did you know to do that? I
9 mean, how did you even know that that thing
10 existed? Who told you about that?

11 A. It was provided to me by the
12 plaintiffs' attorneys.

13 Q. Okay. And what did they give
14 you? Did they give you his ruling?

15 A. Yes, sir.

16 Q. Okay. And so is it your
17 position that his ruling is the -- the --
18 states the law with regard to the regulatory
19 obligations of the various defendants in this
20 case?

21 A. Well, my understanding is his
22 ruling kind of breaks down the Masters
23 Pharmaceutical case and the appellate court
24 decision that resulted from that case, and he
25 kind of gives a general understanding of what

1 my -- my section was the suspicious order
2 system, how it works, the reasonableness of
3 it, and the maintenance of effective
4 controls. And his was an interpretation.

5 Q. An interpretation?

6 A. Of -- well, I wouldn't say an
7 interpretation because obviously he's not
8 going to interpret the appellate court
9 ruling. I think it's kind of a common sense
10 or just kind of a good written product of the
11 Masters Pharmaceutical case. That was my
12 investigation.

13 Q. And so you referenced Discovery
14 Ruling 12, and then I didn't see any
15 reference to his next ruling on this motion,
16 which had to do with withdrawing a portion of
17 Discovery Ruling 12.

18 Do you remember that?

19 A. I don't think I reviewed that.
20 I wasn't provided that.

21 Q. Okay. So you weren't provided
22 with Special Master Cohen's follow-up ruling
23 on Discovery Ruling 12, correct?

24 A. I do not recall that.

25 Q. And you wouldn't have known

1 about it -- I mean, you wouldn't have known
2 to ask for it because you didn't know it
3 existed, right?

4 A. Right. I was provided so many
5 documents, I don't have any recollection of
6 reviewing it. But I'd like to leave the slim
7 chance that maybe I did and I just don't
8 recall. I know it's not referenced in my
9 report.

10 Q. Right. Okay. So maybe there's
11 a slim chance. I didn't see it in any of the
12 documents.

13 A. Well, you know what, I'm
14 drawing a blank on that particular, but there
15 is a possibility that I guess at some point.
16 I get so many of these documents that it may
17 have been provided to me.

18 Q. Okay. So you don't know that
19 Special Master Cohen wrote that his -- and
20 I'm just reading from his follow-up report,
21 which you have -- his follow-up ruling, which
22 you did not see: Second, the discourse was
23 not meant to be authoritative or conclusive
24 on how all suspicious order monitoring
25 systems must work. As distributors note,

1 resolution of whether their SOMS met
2 applicable legal requirements over time is a
3 question for another day.

4 So you didn't see that?

5 MR. FULLER: Form.

6 A. No.

7 BY MR. NICHOLAS:

8 Q. Okay. And you didn't --

9 A. So -- I'm sorry.

10 Q. Well, I just want to know
11 whether you remember seeing that.

12 MR. FULLER: You can finish
13 answering that question. Go ahead.

14 MR. NICHOLAS: Yeah.

15 A. I don't remember seeing that
16 particular statement.

17 BY MR. NICHOLAS:

18 Q. Okay. And so you also don't
19 remember -- or do you remember seeing this
20 statement: In sum, distributors are correct
21 that Discovery Ruling No. 12 was exactly
22 that, a discovery ruling, and not a
23 definitive pronouncement on their legal
24 obligations.

25 Do you remember seeing that?

1 MR. FULLER: Form.

2 A. I do not recall seeing that.

3 MR. NICHOLAS: Okay. Let's
4 take our first break, if that's okay.
5 Five minutes.

6 THE VIDEOGRAPHER: Going off
7 the record, 10:26 a.m.

8 (Recess taken, 10:26 a.m. to
9 10:38 a.m.)

10 THE VIDEOGRAPHER: We're back
11 on the record. The time is 10:39 a.m.

12 BY MR. NICHOLAS:

13 Q. Mr. Rafalski, it's correct,
14 isn't it, that there was a time when the DEA
15 approved suspicious order monitoring
16 programs, correct?

17 A. Sir, I'm never aware of any
18 time where there was an approval of a
19 particular system.

20 Q. Okay. If there was ever an
21 approval of a particular system, that would
22 be like highly relevant information, right?

23 A. Well, it could be, but I'm just
24 testifying from my review of records and my
25 experience, mainly my expertise and my

1 training with the DEA where it's clearly
2 stated from the day I was employed that the
3 DEA doesn't approve systems.

4 Q. Okay. Did you ever review any
5 documents in this case that have been
6 produced in the case having to do with
7 AmerisourceBergen's suspicious order
8 monitoring system?

9 A. I'm sure I did in the
10 preparation of my report. If you want to --
11 is there a particular document that you want
12 to...

13 Q. There is.

14 MR. NICHOLAS: Let me start
15 with -- let me start with Tab 17. So
16 just for everybody's information, we
17 have -- we didn't bring like 20 of
18 these things, all right, but I have
19 one for the witness. I have one for
20 me. I have one for Mr. Fuller and
21 then what do we have? Maybe one
22 other? We have six copies. The rest
23 of you guys can share.

24 MR. FULLER: They're stickers.
25 You just peel them off and put them

1 on.

2 MR. NICHOLAS: Okay.

3 (Whereupon, Deposition Exhibit

4 Rafalski-1, 9/30/96 Zimmerman Letter

5 ABDCMDL00215791 - ABDCMDL00315794, was

6 marked for identification.)

7 BY MR. NICHOLAS:

REDACTED

REDACTED



13 Q. Okay. And you can take a
14 minute to review the report -- to review the
15 letter if you need to, but let me start by
16 asking you: Have you seen this letter
17 before?

18 A. I believe I have.

19 Q. Okay. Then so you recall its
20 contents?

21 A. No, I'd like an opportunity to
22 read it, if I could have a minute or two.

23 Q. Sure, why don't you take a
24 minute to look at it.

25 (Document review.)

REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED

10 MR. NICHOLAS: Not the biggest
11 point in the world. I was really just
12 bickering back and forth with you
13 because you said something, so I'm
14 going to --

15 THE WITNESS: I don't want to
16 bicker. I just want to give you some
17 facts.

18 MR. NICHOLAS: I know. I'm
19 self-correcting.

20 THE WITNESS: I apologize if I
21 engaged in bickering.

22 MR. NICHOLAS: As do I.

23 BY MR. NICHOLAS:

REDACTED

REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



24 Q. That's okay. Let's just -- I
25 want to stick with --

1 A. Just -- you characterized that
2 I ignored it, and I'm pretty sure that I have
3 a section in my report about that

REDACTED

12 Q. No, you can go back -- your
13 lawyer can do that with you later. I have
14 another question.

15 MR. FULLER: No, if you want to
16 go to the report --

17 THE WITNESS: Well, if --

18 MR. NICHOLAS: No, no, no.

19 MR. FULLER: Hold on. You
20 don't ask permission. You go to your
21 report.

22 THE WITNESS: I'd like to
23 clarify that, so...

24 MR. NICHOLAS: Okay. Well,
25 looks like you and Mr. Fuller are

1 taking over the questioning for a
2 minute, but...

3 MR. FULLER: Just like any
4 expert, he's allowed to go to his
5 report if he wants to go to his
6 report.

7 MR. NICHOLAS: Of course.
8 You're going to be able to question
9 him at the end of this thing. You can
10 question him to your heart's desire.

11 (Document review.)

12 A. So it's on page 82, the second
13 paragraph.

14 BY MR. NICHOLAS:

15 Q. Okay.

REDACTED

REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



18 A. Well, let me confirm that.

19 Q. No, you know something --

20 MR. FULLER: No, no.

21 MR. NICHOLAS: I'm not asking
22 you --

23 MR. FULLER: Counsel, you
24 asked. You asked. You asked the
25 question.

1 MR. NICHOLAS: Counsel, I'm not
2 asking him to confirm it. You can go
3 back to it and he can do it later.
4 I'm not running clock here like that,
5 so we can keep going and we will keep
6 going.

7 Just give me one second.

8 THE WITNESS: Sure.

9 BY MR. NICHOLAS:

10 Q. Had you seen this letter before
11 preparing your report, would you have viewed
12 it as relevant information to be included in
13 the report?

14 A. Well, the opinion that I was
15 offered -- I was requested to make wasn't an
16 analysis of the DEA's actions; it was whether
17 or not the systems in place were effective.

18 So it wouldn't have changed my
19 opinion on whether the system utilized by
20 AmerisourceBergen met the regulatory
21 compliances.

22 Q. I didn't ask you whether this
23 letter would change your opinion. I did ask
24 you whether, had you seen this letter, you
25 would have thought it relevant for purposes

1 of inclusion in your report. That's my
2 question.

3 A. I'd like to just stay with my
4 previous comment. Other than by including it
5 or not including it, it wouldn't have changed
6 my opinion on whether the system utilized was
7 effective or met regulatory compliance.

REDACTED



REDACTED



REDACTED



REDACTED



19 Q. Okay. Before we leave that
20 subject, you are familiar with the letters
21 that Mr. Rannazzisi wrote to registrants in
22 2006 and 2007, right?

23 A. Yes, sir, I am.

24 Q. Okay. And I'm going to ask you
25 just to take a look for a very limited

1 purpose right now at his December 27th, 2007
2 letter, which we'll mark, I guess, as
3 Exhibit 4.

4 (Whereupon, Deposition Exhibit
5 Rafalski-4, 12/27/07 Rannazzisi
6 Letter, ABDCMDL00269685 -
7 ABDCMDL00269694, was marked for
8 identification.)

9 MR. NICHOLAS: There you go.

10 THE WITNESS: Thank you.

11 BY MR. NICHOLAS:

12 Q. And I'm really only going to
13 ask you about the -- the last sentence of the
14 second full paragraph. You see it?

15 A. Yes, sir. Would you like me to
16 read it?

17 Q. Yeah.

18 A. Past communications with DEA,
19 whether implicit or explicit, that could be
20 construed as approval of a particular system
21 for reporting suspicious orders should no
22 longer be taken to mean that DEA approves a
23 specific system.

24 Q. Now, Mr. Rannazzisi is writing
25 this letter to registrants in 2007, correct?

1 A. Yes, sir.

2 Q. And he says that past
3 communications that could be construed as
4 approval should no longer be taken to mean
5 the DEA approves a specific system.

6 Do you see that?

7 A. Yes, sir.

8 Q. So when he says that these
9 communications should no longer be taken to
10 mean that the DEA approves a specific system,
11 do you agree that prior to this letter, such
12 communications were taken as approvals and
13 the DEA understood that?

14 MR. FULLER: Form.

15 A. Well, I'm not sure what
16 Mr. Rannazzisi knew or didn't know when he
17 composed the letter. My interpretation when
18 I read that is it's kind of just a
19 notification to -- you know, to the industry.

20 I'm aware that -- in my
21 experience that oftentimes you're on-site or
22 you're having contact with a registrant and
23 the registrant makes -- this would be the
24 implicit -- would make some assumptions on
25 what you're saying or what you're approving

1 or if you don't find an error, that that --
2 or a problem, that that means that it's
3 approval.

4 So the explicit, you know,
5 that's a different situation, so I -- I just
6 think it's just a clarification. I'm not
7 aware that he was specifically talking about
8 any particular communication.

9 BY MR. NICHOLAS:

10 Q. It says should no longer be
11 taken.

12 A. It does say that, yes, sir.

13 Q. Yeah. So that means that
14 previously he knew that it was being -- that
15 these -- that these communications were being
16 taken as approvals, right?

17 MR. FULLER: Object to form.

18 A. I don't know what he thought.

19 BY MR. NICHOLAS:

20 Q. Okay.

21 A. Or if that was his intention
22 with that statement, that he assumed that was
23 occurring.

24 Q. Well, that's -- I'm just sort
25 of going by the words. That's how it reads,

1 isn't it?

2 A. That's how it reads, but as I
3 testified to earlier, you know, I had several
4 cases where there were comments made or there
5 was understandings made with contacts between
6 registrants and companies where they believed
7 that something was approved or was ordered of
8 them, which was not accurate.

9 So I'm not -- but I'll just go
10 back and say I'm not exactly sure what
11 Mr. Rannazzisi's intent was with that
12 particular statement. Just it's clear
13 what -- moving forward what his intent was.

14 Q. Now, Mr. Rannazzisi also sent a
15 letter on September 27th of 2006 to the
16 various registrants, and I'll just read it.
17 I don't even have to mark it. I can just
18 read one sentence from it and ask you whether
19 you agree with it, because it's just a
20 general statement.

21 The sentence that
22 Mr. Rannazzisi wrote is: DEA recognizes that
23 the overwhelming majority of registered
24 distributors act lawfully and take
25 appropriate measures to prevent diversion.

1 Do you agree with that
2 statement that Mr. Rannazzisi made?

3 MR. FULLER: Form, outside of
4 his scope.

5 A. Can you read it one more time
6 for me?

7 BY MR. NICHOLAS:

8 Q. Yes.

9 DEA recognizes that the
10 overwhelming majority of registered
11 distributors act lawfully and take
12 appropriate measures to prevent diversion.

13 A. Well, based on my work on this
14 matter and my review of records and systems,
15 which I didn't have any previous knowledge of
16 previous to when I did that, I would probably
17 disagree with that statement by
18 Mr. Rannazzisi, in looking at the historic
19 failures by the companies to be in compliance
20 with the suspicious order situation -- or
21 regulation and just a general broad
22 maintenance of effective controls to prevent
23 diversion.

24 MR. NICHOLAS: It's been --
25 well, let's take a short break. We'll

1 go another 45 minutes after that and
2 have lunch, if that's okay.

3 THE VIDEOGRAPHER: Going off
4 the record, 11:34 a.m.

5 (Recess taken, 11:34 a.m. to
6 11:45 a.m.)

7 THE VIDEOGRAPHER: We're back
8 on the record at 11:45 a.m.

9 BY MR. NICHOLAS:

10 Q. The DEA requires the retention
11 of records to be for at least two years; is
12 that correct?

13 MR. FULLER: Form.

14 BY MR. NICHOLAS:

15 Q. By policy?

16 A. Well, by regulation --

17 Q. By regulation.

18 A. -- the requirement is -- and
19 that two-year applies to required records.
20 So within the CFR, there are certain records,
21 examples would be biannual inventories, order
22 forms. Any of the records that are in the
23 records section of the CFR have a two-year
24 retention.

25 And there's a carve-out that if

1 a state has a longer retention period, that
2 the registrant could be subjected to that,
3 but that two years only applies to those
4 certain records that are cited in the CFR.

5 Q. So -- but the carveout that
6 you're talking about doesn't apply to
7 suspicious order reports, right? That's
8 within the two -- that's subject to the
9 two-year regulation?

10 MR. FULLER: Form.

11 A. No. The suspicious order
12 reports aren't part of the two-year
13 retention.

14 BY MR. NICHOLAS:

15 Q. They don't have to be retained
16 at all?

17 A. Well, under my opinion, it
18 would be they would be retained forever.

19 Q. Right, but, I mean, the
20 regulation doesn't require -- I understand
21 that might be your opinion, but is there any
22 regulation that says they have to be retained
23 for any length of time?

24 A. I would say the maintenance of
25 effective controls to prevent diversion would

1 be applicable to say that they should retain
2 the suspicious order reports or any due
3 diligence related to them.

4 Q. There are specific sections --
5 there are specific regulations that address
6 records retention, correct?

7 A. Yes, sir.

8 Q. And those --

9 MR. FULLER: Form.

10 BY MR. NICHOLAS:

11 Q. -- regulations identify the
12 categories of records that have to be kept
13 and for how long, correct?

14 MR. FULLER: Form.

15 A. The CFR does address that, but
16 those are the required records. For example,
17 there are some records that registrants keep
18 in the course of their business that aren't a
19 required record. So just so we're on the
20 same understanding as to -- the two-year
21 retention is only under those required
22 records; dispensing records for a dispensing
23 doctor, two-year retention; biannual
24 inventories, order forms, those are all part
25 of the required records.

1 BY MR. NICHOLAS:

2 Q. So the things we're talking
3 about now, suspicious order reports or due
4 diligence documents, are not part of the
5 kinds of records that are required to be
6 retained under the CFR and the regulations?

7 A. Well --

8 Q. That's a yes or a no.

9 MR. FULLER: Object to form.
10 He's already testified they were.

11 MR. NICHOLAS: That's not what
12 he said.

13 Go ahead.

14 THE WITNESS: So could you
15 restate the question? I'm sorry.

16 BY MR. NICHOLAS:

17 Q. Does the CFR or its regulations
18 require in writing and as identified
19 suspicious order reports?

20 MR. FULLER: Form.

21 MR. NICHOLAS: I'll ask it
22 again. It was a crappy question.

23 BY MR. NICHOLAS:

24 Q. Does the CFR identify
25 suspicious order reports as among the

1 documents that have to be retained for at
2 least two years?

3 A. I would say yes, under the
4 maintenance of effective controls, but I
5 think there's not a lot of clarity on whether
6 that is essentially a required record.

7 Q. Does the CFR identify due
8 diligence documents as documents that are
9 required to be retained for at least two
10 years?

11 A. I'm going to respond the same:
12 Under maintenance of effective controls, I
13 think that requirement requires the retention
14 of due diligence records. The CFR doesn't
15 speak specifically to a due diligence record,
16 but that would be a record that would be
17 maintained within the requirement of that
18 regulation.

19 Q. For at least two years?

20 A. Again, my opinion, they should
21 be kept permanently.

22 Q. No, I'm not asking about your
23 opinion. I'm asking under -- what the
24 requirement is under the law as you
25 understand it.

1 A. Under the regulation as I
2 understand it --

3 Q. Yeah.

4 A. -- it doesn't speak
5 specifically to due diligence records. So
6 I -- a two-year retention -- if a registrant
7 was to review the CFR, there's no mention of
8 a due diligence record, so I would say it's
9 not two years.

10 But again, I'd just restate
11 that I would see no reason why they wouldn't
12 retain them indefinitely.

13 Q. Okay. I just want to go back
14 for one second to when you said several times
15 that -- you talked about your understanding
16 about how the DEA -- or your belief that the
17 DEA does not -- has never given approvals of
18 suspicious order monitoring systems, and you
19 said that the manual said you're not supposed
20 to and all that.

21 When did you start at the DEA?

22 A. 2004.

23 Q. Okay. When you refer to the
24 manuals, to the Diversion Control Manual, you
25 were referring to a manual that you read in

1 2004, right? Or after.

2 A. Well, I -- I was also referring
3 to the manual that I read as part of my
4 opinion in 1996, and my -- and my opinion on
5 the suspicious orders on approval, it's
6 broader than just the manuals. Multiple
7 trainings, my witnessing of a distributor
8 briefing, the comments made in the training
9 provided; also, my review of communication
10 that I believe Mr. Gitchel made in 1984 where
11 he made that statement.

12 So -- plus my on-the-job
13 training, my -- there's never been a time
14 where I can ever remember that DEA -- there
15 was a comment made to me that the DEA had
16 approved suspicious order systems.

17 Q. Wait, you reviewed a statement
18 that Mr. Gitchel made in 1984?

19 A. I don't know if it was a
20 statement. He made -- I believe he was the
21 one who made a written comment to NWDA in
22 regards to a suspicious order reporting
23 program that was worked on way back then, and
24 he made a comment about not being able to
25 approve any specific.

1 Q. Is that in your report?

2 A. I believe it is.

3 Q. Okay. No, no --

4 A. No, I'd like to talk to you
5 about it.

6 Q. I just want to know if it's in
7 your report.

8 A. Yeah, but --

9 Q. Is it -- that's a yes or no.
10 You can check to see if it's in your report,
11 yes or no.

12 A. Well, let me review my report.

13 MR. NICHOLAS: It's a 200-page
14 report. We can go off the record and
15 stop the clock running during this
16 review.

17 MR. FULLER: No, we need to
18 stay on the record.

19 (Document review.)

20 MR. FULLER: I think it's on
21 page 32.

22 THE WITNESS: I'm getting
23 there. I don't want to waste time.

24 (Document review.)

25 A. So I discussed that

1 communication on page 32 of my report.

2 BY MR. NICHOLAS:

3 Q. Okay. Hold up. Yeah.

4 I just want to know -- I mean,
5 all I really wanted to know is did you put in
6 your report that Mr. Gitchel said in 1984
7 that the DEA doesn't approve --

8 A. No, I think I may have
9 misspoke. I think it was in regards to
10 stopping shipments of --

11 Q. Okay.

12 A. -- orders.

13 Q. Okay. All right. That's fine.

14 A. That's why I wanted to review
15 my report, to make sure.

16 Q. This was an instance where you
17 reviewed your report and found something --
18 and found something that I agree -- supported
19 my point, so that's good. I should let you
20 review your report more often.

21 A. Yeah, you tried to stop me.
22 But I just want to be factually correct.
23 It's an important subject.

24 Q. I appreciate it.

25 A. And I had a recollection that

1 that was discussed, but it was about stopping
2 an order, so...

3 Q. All right. So since we are
4 talking about sort of what -- since you just
5 sort of brought up the shipping requirement.

6 A. Yes, sir.

7 Q. First of all, just so the -- so
8 we've got it on the record, what do you
9 understand -- it's a weird word, because it's
10 a shipping requirement, but it really -- it's
11 a reference to not shipping.

12 So can you just explain what
13 the shipping requirement is to your
14 understanding?

15 A. Well, first, I've never --
16 there's never really been a formal term. A
17 shipping requirement, I don't know if that's
18 an industry term or just somehow got created,
19 but it never was referred to as just a
20 shipping requirement.

21 I mean, it's -- it's the mere
22 fact that when a company uses a suspicious
23 order system and identifies a suspicious
24 order, they don't ship that order until they
25 dispel the suspicion about it and whether or

1 not it's going to be diverted to ensure that
2 gets properly distributed.

3 Q. Okay. So let me ask a couple
4 of basic questions here.

5 Does the CFR or the regulations
6 related to the CFR on this subject say
7 anywhere that there is a requirement that
8 distributors not ship suspicious orders?

9 A. I think they give guidance to
10 distributors under the maintenance of
11 effective controls. Only saying that because
12 if a distributor discovers a suspicious
13 order, to ship it without dispelling the
14 suspicion, that kind of violates the
15 maintenance of effective controls.

16 So I don't want to say it's
17 just a commonsense interpretation, but to
18 identify something suspicious that is
19 suspicious of diversion and then just
20 shipping it without stopping it and
21 dispelling it, that's at the core of that
22 regulation.

23 Q. Does the --

24 A. And the law.

25 Q. Does the regulation say

1 anything about ship -- does the regulation in
2 words, words, say anything about shipping?

3 A. No, in words, the regulation
4 does -- and just the --

5 Q. It does or does not?

6 A. It does not say the word
7 "shipping."

8 Q. Okay.

9 A. But again, I go back to the
10 maintenance of effective controls, and
11 secondly, it's been since the day I started
12 at DEA, that's been the interpretation of the
13 DEA, and I think there's been several
14 communications, Mr. Rannazzisi's letters.

15 Q. Okay.

16 A. All the way back -- now I can
17 go back to Mr. Gitchel's letter in 1984,
18 about stopping an order because that was the
19 topic that I discussed -- that I confused on
20 your earlier question.

21 Q. Do you -- is it your testimony
22 that the decision as to whether to ship or
23 not to ship an order that's been reported to
24 the DEA is left to the discretion of the
25 distributor?

1 A. So I think the discretion on
2 whether to ship or not ship is solely the
3 decision of the distributor. The DEA doesn't
4 inform a distributor if or when to ship an
5 order or not to ship an order. So the answer
6 to that would be yes.

7 Q. And if a distributor asks the
8 DEA -- if the distributor came to the DEA and
9 said, we've got this order, we have questions
10 about it, should we ship it or not ship it,
11 the DEA won't answer that question?

12 A. So I'm not sure that I'm
13 comfortable speaking for the entire DEA, but
14 how I'd like respond to that is through my
15 experience and what has occurred in the past.

16 So there may be a time when you
17 receive a call from a registrant that may ask
18 a question like that or a similar question,
19 so generally, you can -- first, I would
20 always state there's two -- two situations,
21 and we're just going to talk about suspicious
22 orders -- or, I mean, about distributions.

23 And first, I'll always state
24 that I can't tell a distributor when to ship
25 or not to ship, but I may ask a lot of

1 questions of the distributor that makes it
2 easier for them to make that decision.

3 Q. Okay.

4 A. Now, that's my personal
5 experience. I'm not speaking that the entire
6 DEA does that.

7 Q. Now, you spent some time in
8 your report talking about the Masters
9 decision; is that correct?

10 A. Yes, sir.

11 Q. That decision came out in 2017,
12 correct?

13 A. Yes, sir. Right after I
14 retired.

15 Q. Although you were on the team
16 that investigated Masters, right?

17 A. I was. There was no team. It
18 was just me.

19 Q. Well, then, I want to say
20 there's no I in team, but somehow that
21 doesn't quite fit, but I'd like to say it
22 anyway.

23 A. Well, I would say that there's
24 always another investigator with me, but it
25 was my case.

1 Q. Okay. Now, Masters, your
2 investigation of Masters was of
3 Masters Pharmaceutical, correct?

4 A. Yes.

5 Q. It was not -- you were not
6 investigating any other distributors in
7 connection with that, correct?

8 A. No, that's not actually a
9 correct statement. I would disagree with the
10 statement. During the course of that
11 investigation, there were some -- they call
12 them gray distributions. I don't know, maybe
13 that's an internal DEA. So that would be
14 distributions from Masters to other
15 distributors.

16 So I -- you know, that didn't
17 lead me personally to investigate other
18 distributors, but it did -- it did cause me
19 to make notifications about other -- to other
20 offices about other distributors.

21 Q. You did not -- my question to
22 you was: You were only investigating
23 Masters Pharmaceutical, right?

24 A. Yes, sir.

25 Q. Okay.

1 A. That was the assignment of the
2 investigation.

3 Q. All right.

4 A. Maybe I misunderstood your
5 question. I didn't want you to think that I
6 didn't look at any distributions of other --
7 to other distributors or --

8 Q. And Masters, the company,
9 ultimately challenged the DEA's findings from
10 your investigation, right?

11 A. Yes, they did.

12 Q. And in so doing, they took the
13 case up to the D.C. Circuit, right?

14 A. Yes, sir.

15 Q. And the case before the
16 D.C. Circuit was about Masters's system
17 alone, right?

18 A. Well, I think the factor that
19 caused it to go to the D.C. court was
20 Masters's system and their use of the system,
21 but I think to me, or more importantly, I
22 believe, to the DEA, I think it was a
23 reiteration of what the expectations were of
24 registrants, and because sometimes I see some
25 commenting that that was the -- that's the

1 way that the interpretation is moving
2 forward. I believe that's the way the
3 interpretation of the regulations always was,
4 always was in place.

5 Q. But the issue in Masters was
6 Masters's compliance with its own policies
7 and procedures, right?

8 MR. FULLER: Objection, form,
9 misstates the case.

10 A. Well, it's at the core of one
11 of the issues or at the core of the
12 administrative hearing.

13 BY MR. NICHOLAS:

14 Q. Masters came out in 2017. Did
15 I ask you that already?

16 A. It did. I think it was the
17 week after I retired.

18 Q. That's right. You said that
19 too.

20 Now, when the Masters decision
21 came out, do you recall that the industry was
22 confused by the decision?

23 MR. FULLER: Form. How would
24 he know?

25 A. I'm not aware of any

1 information that would make that a true
2 statement.

3 MR. NICHOLAS: Okay. We'll
4 mark as our next exhibit, Exhibit 5.

5 (Whereupon, Deposition Exhibit
6 Rafalski-5, 2/6/18 Nicholson Letter,
7 MCKMDL00561146 - MCKMDL00561147, was
8 marked for identification.)

9 BY MR. NICHOLAS:

10 Q. And while you're looking at it,
11 I'll just say for the record, this is a
12 letter dated February 6th of 2018 to Demetra
13 Ashley, the acting assistant administrator
14 for Diversion Control Division of the DEA.

15 It is written -- it is signed
16 by Kevin Nicholson, the vice president for
17 policy -- public policy and regulatory
18 affairs for the National Association of Chain
19 Drug Stores.

20 (Document review.)

21 A. Okay. I've read the letter.
22 I've also read this previously.

23 BY MR. NICHOLAS:

24 Q. Okay. Does this refresh your
25 memory or cause you to want to change your

1 answer about the question of whether industry
2 was confused by the Masters decision?

3 MR. FULLER: Form.

4 A. No, it does not.

5 BY MR. NICHOLAS:

6 Q. Okay. Can you look at the
7 first paragraph, the second sentence, from
8 the second sentence to the end.

9 A. Starting with "The National"?

10 Q. Yeah.

11 A. Like me to read it?

12 Q. Yeah, that would be great.

13 A. The National Association of
14 Chain Drugstores (NACDS), respectfully
15 request that DEA promulgate regulations to
16 affected registrants regarding their
17 suspicious order monitoring regulatory
18 obligations in light of the Masters decision.

19 We are aware that the DEA has
20 been working on regulations to clarify
21 registrants' responsibilities under
22 21 CFR 1301.74(b).

23 We believe the D.C. Circuit's
24 ruling in the Masters case necessarily
25 increases the urgency of DEA's promulgation

1 of guidance concerning affected registrants'
2 suspicious order monitoring responsibilities.

3 Q. Are you aware that the DEA has
4 been working on regulations to clarify
5 registrants' responsibilities under
6 21 CFR 1301.74(b)?

7 A. I did review either a document
8 or a deposition, and I don't recall of which,
9 that spoke to this, and I believe there was
10 one document that indicated they were, but
11 another document or a deposition which
12 indicated they no longer were.

13 So I guess that's kind of an
14 ambiguous answer, but if you were to ask me
15 what I believe is occurring right now, I do
16 not believe they're working on changing
17 1301.74(b). That would be my opinion.

18 Q. Are you aware that for a period
19 of time from 2015 to 2019, they were working
20 on a revision to the regulation?

21 MR. FULLER: Form.

22 A. I'm not aware of that.

23 MR. FULLER: Form. And as far
24 as the Touhy compliance, let's just
25 make sure, Mr. Rafalski, that you're

1 basing it on information that you
2 gained from this litigation and not
3 your work at the DEA.

4 BY MR. NICHOLAS:

5 Q. So you're unaware of this; is
6 that right?

7 A. That they were working on the
8 regulation?

9 Q. Yeah.

10 A. Well, I don't have any direct
11 recollection that someone told me that the
12 DEA is working on this particular regulation,
13 but at the DEA, up in policy, and they're
14 always working on regulations, and it's not
15 something that's communicated to the field.
16 So I just -- I don't really have any
17 knowledge whether they were or weren't.

18 Q. Well, in your review of all the
19 documents in this case, the documents that
20 you were provided, did you see either a
21 report from the GAO or a summary of a report
22 from the GAO concerning diversion control
23 matters?

24 A. I believe I did.

25 Q. Do you recall that the GAO

1 specifically recommended that the DEA revise
2 the regulation -- revise the regulation
3 pertaining to suspicious orders to provide
4 greater clarity?

5 A. I don't really want to speak on
6 that document. Do you have a copy?

7 Q. I do. But right now I want to
8 know whether you remember it.

9 A. Well, no. Well, I don't
10 remember that -- I remember the document. I
11 don't remember that specific statement. And
12 I don't know that it addressed back to 2015
13 unless we've moved from the previous
14 question, so...

15 Q. Do you recall that the GAO had
16 three specific recommendations that it issued
17 to the DEA on the topic of improving
18 communication with registrants and industry?
19 Do you recall that?

20 A. I remember there were
21 recommendations.

22 Q. Do you remember that there were
23 three of them, only three of them?

24 A. No, sir.

25 Q. And do you remember that one of

1 the three was to revise the regulation
2 pertaining to suspicious order reporting in
3 order to provide greater clarity?

4 A. I'd like to see the document.
5 I don't have independent recollection of that
6 statement.

7 Q. Okay. Let's see if I can find
8 it.

9 Before we look at it, if indeed
10 the GAO -- I think GAO stands for Government
11 Accounting Organization; is that right?
12 Government --

13 A. Accountability.

14 Q. -- Accountability --

15 A. Office.

16 Q. -- Office. I should know these
17 things.

18 If that was the GAO's -- and
19 what is the Government Accountability
20 Office's job? Do you know?

21 A. Kind of exactly what it says.
22 They're tasked with -- and I don't know what
23 initiates them to come in and do an
24 accountability study, whether it's a
25 directive from the legislature or how they go

1 about doing an accountability, but they come
2 in to organizations within the government and
3 evaluate topics at the -- I'm just not sure
4 at the request of who. Maybe the document
5 would say that.

6 Q. So in this case they did an
7 accountability study of the DEA, correct?

8 A. I do remember that they did a
9 study, and I think it was on the -- I don't
10 think it was specific to this particular
11 topic. I think it was of the organization.

12 My recollection -- well, I
13 don't want to speak about my recollection if
14 we could just use the document.

15 Q. Okay. Let's just take a look
16 at it.

17 (Whereupon, Deposition Exhibit
18 Rafalski-6, 5/10/19 GAO Publication on
19 Prescription Drugs [No Bates], was
20 marked for identification.)

21 BY MR. NICHOLAS:

22 Q. What I'm going to show you is
23 something from the GAO's website, actually,
24 and you can just -- we can identify it. Just
25 the heading of it is Prescription Drugs:

1 More DEA information about registrants'
2 controlled substances roles could improve
3 their understanding and help ensure access.

4 That's the heading of the
5 document.

6 A. Uh-huh.

7 MR. FULLER: For the record,
8 it's not the actual GAO report,
9 correct?

10 MR. NICHOLAS: No, it's a
11 website summarizing aspects of the
12 report.

13 MR. FULLER: Got it. Thanks.

14 BY MR. NICHOLAS:

15 Q. And this is dated May of 2019,
16 so I don't want to misrepresent that this is
17 a document that came out in 2015, although
18 that document is -- that date is on here, but
19 this I believe was run off on May of 2019.

20 And if you go to the second
21 page, and the second recommendation, the
22 recommendation reads as follows: In order to
23 strengthen DEA's communication with and
24 guidance for registrants and associations
25 representing registrants as well as

1 supporting the Office of Diversion Control's
2 mission of preventing diversion while
3 ensuring an adequate and uninterrupted supply
4 of controlled substances for legitimate
5 medical needs, the deputy assistant
6 administrator for the Office of Diversion
7 Control should solicit input from
8 distributors or associations representing
9 distributors and develop additional guidance
10 for distributors regarding their roles and
11 responsibilities for suspicious order
12 monitoring and reporting.

13 Do you see that?

14 A. Yes, I do.

15 Q. Okay. And the comment that the
16 DEA provided in response to that
17 recommendation was as follows: In
18 February 2018, DEA reported that the agency
19 had reviewed and revised the current
20 regulation regarding suspicious orders and
21 that the revised draft rule was undergoing
22 internal DEA review. DEA reported in August
23 of 2018 that they anticipated sending the
24 draft rule to the Department of Justice's
25 Office of Legal Policies by the end of the

1 first quarter of fiscal year 2019.

2 We plan to continue to monitor
3 the agency's efforts in this area and this
4 recommendation remains open.

5 So you see that?

6 A. I see that.

7 Q. So it's clear from this that
8 the -- that the DEA was, in fact, for some
9 period of time working on revising the
10 regulation pertaining to suspicious orders,
11 correct?

12 A. Well, when you read this, I
13 mean, that's the assumption you would make.
14 I'm not aware of any changes or how they
15 change it. And it doesn't influence my
16 opinion on what the responsibilities were in
17 regards to my report or what the requirements
18 of the regulation were all the way back till
19 it came into place in 1971.

20 Q. Well, we have a -- we just
21 looked at a letter from the National
22 Association of Chain Drug Stores in which
23 that organization, on behalf of various chain
24 drug stores, expressed a desire for greater
25 clarity in the regulation.

1 You saw that, right?

2 A. Yes, sir.

3 Q. Okay. And now we have the GAO
4 acknowledging -- I'm sorry, we have the DEA
5 acknowledging in response to a recommendation
6 from the GAO that they are, in fact -- that
7 they were, in fact, working on a revision to
8 the regulation, correct?

9 A. That's what that says, yes,
10 sir.

11 Q. Okay. And do you know whatever
12 became of that revised regulation, proposed
13 revised regulation?

14 A. I don't have any direct
15 knowledge or recollection or anyone has ever
16 told me what the status was of that
17 regulation, but I'd just like to reiterate,
18 whether or not the regulation has changed or
19 going to be changed, it doesn't change my
20 opinion because -- because of that, of what
21 was required of these companies during the
22 timeline of my report.

23 I would say that I think the
24 DEA was providing a lot of communication to
25 the industry, and I -- I don't know that they

1 provided it to the NACDS. I know it seemed a
2 little unusual that they were having
3 individual meetings with registrants, doing
4 distributor briefings. They do conferences,
5 industry conferences.

6 And it's been my knowledge and
7 my experience that any registrant that
8 requests a meeting with the DEA at
9 headquarters, they're always provided. Maybe
10 not as timely as they'd like, but I'm not
11 aware of the DEA just refused to ever meet
12 with anyone.

13 Now, I'm a little concerned
14 because I don't really in my experience deal
15 with organizations that aren't registrants.
16 I'm a little cautious about -- or in the DEA
17 realm of dealing with -- I don't know if this
18 is a lobbying group or if it's just a trade
19 association, that they would make comments to
20 trade associations when I think they would
21 rather directly deal with registrants, so...

22 Q. Is it significant to you in any
23 way that the DEA, for a period of several
24 years, worked on revising the regulation
25 pertaining to suspicious order reporting and

1 monitoring? Is it significant to you in any
2 way?

3 A. In a broad answer to that
4 question, I think the DEA should always be
5 looking at and evaluating regulations and how
6 they affect the industry, not just a
7 suspicious order system.

8 In regards to how they were
9 going to change it or what new statement they
10 were going to make, I have no awareness of
11 that, but I would hope that the DEA or any
12 governmental organization wouldn't just have
13 regulations that they just allow to remain
14 static if they, you know -- I would hope
15 they're always under review.

16 Q. Well, this regulation had
17 remained the same in language since 1974?

18 A. '1.

19 Q. '1, '71?

20 A. 1971.

21 Q. So not one word of it had been
22 changed from 1971 until the present -- until
23 the present, correct?

24 A. Well, it's my opinion there's a
25 reason for that, and --

1 Q. So I'm just asking you whether
2 it's correct that it hasn't changed since
3 1971.

4 A. Well --

5 Q. Has it changed since 1971?

6 A. It's exactly the same as 1971.
7 And I'd like to just reiterate --

8 Q. You can, but wait a minute.
9 Hold on.

10 And do you believe that it is
11 appropriate to update that language?

12 MR. FULLER: So object to the
13 form of the last question prior to
14 this and cutting off the witness. He
15 has a right to finish his answers, and
16 let the record reflect that the
17 answers are incomplete as taken.

18 MR. NICHOLAS: Understood.

19 THE WITNESS: Could you state
20 your -- this question one more time,
21 please? I'm sorry.

22 BY MR. NICHOLAS:

23 Q. Do you believe that it is
24 appropriate to update the language of the
25 regulation?

1 A. I think I stated that in my
2 previous answer. Of this regulation or any
3 regulation?

4 Q. This one.

5 A. No, I think the regulation is
6 fine exactly as it stands.

7 Q. And would you continue to say
8 that if you understood that both industry and
9 people within the DEA have expressed
10 confusion about the meaning of the language?

11 A. Well, I'm only speaking from my
12 experience and conducting my investigations
13 in dealing with registrants, and I guess
14 sometimes when I look at that regulation and
15 if I thought I had the role of being a
16 distributor or a manufacturer, I would want
17 it to be as nonrestrictive and broad as
18 possible to design the best system based on
19 the type of company that I had and the scope
20 of my business model and who my customers
21 were.

22 So I think changing the
23 regulation is a -- I hope that if it is
24 changed, that it takes that into
25 consideration because I don't really think

1 there's a one-size-fits-all.

2 I think there's some
3 expectations of the regulation, but I hope
4 that my experience, again -- I keep harkening
5 back -- is that industry has always been
6 asking for just what is a system and design
7 it. And that's not possible because there's
8 so many different types of businesses and
9 types of customers. It's got to be tailored
10 to the company's business.

11 Q. And the customers change, the
12 customers' businesses change, the hospitals
13 and the doctors change. All that stuff is
14 constantly changing, correct?

15 A. That's exactly my point.

16 Q. Yeah.

17 A. It's never a static industry.
18 The types of diversion change, the types of
19 drugs change, and to make a regulation that
20 would be very restrictive would probably
21 cause diversion.

22 MR. NICHOLAS: We'll just do
23 one more segment here and then we can
24 break for lunch.

25 MR. FULLER: Sure.

1 BY MR. NICHOLAS:

2 Q. Now, you talked a few minutes
3 ago about what you referred to as the DEA
4 distributor initiative briefings?

5 A. Yes, sir.

6 Q. Okay. And you also talk about
7 those in your report; is that right?

8 A. Yes, sir.

9 Q. Okay. And in your report, if I
10 have this correct, you refer to DEA
11 distributor initiative briefings in 2005 and
12 2006 and in 2017; is that right?

13 I'm not sure that you refer to
14 any others. I don't believe you do.

15 A. What -- what part specifically
16 are you...

17 Q. You know, I don't have -- I
18 don't have a page number for you in your
19 report. How about if we do it from memory,
20 and then if you want to look at your report,
21 you can.

22 A. No, I'm not comfortable. I
23 might get a detail wrong.

24 Q. All right.

25 A. So if you're talking about the

1 actual briefings that occurred, they were
2 specific to -- specific to some of the
3 companies, and there was one that occurred in
4 2017.

5 There's -- in my report or in
6 my personal knowledge, I know that they
7 continued on long after 2005, and they went
8 for some period. There was a couple years,
9 two or three years, where they stopped and
10 then resumed.

11 Q. Why did they stop?

12 A. I never was aware they did
13 until working on this case, or actually, I
14 don't know that I ever saw -- let me retract
15 that.

16 I think it was in a deposition
17 that I -- there may have been a discussion
18 where they had stopped for a period of years,
19 and I'm not sure why.

20 Q. Well, did you read about why?
21 I mean, when you read about it, did you read
22 any explanation as to why, in whatever you
23 read?

24 What did you read?

25 A. I read that they had stopped

1 doing it for a period of years and then
2 resumed them, but I don't remember what the
3 reason was stated.

4 Q. Do you remember who said that?

5 A. I don't want to guess, no, sir.

6 Q. Okay. And you don't remember
7 any reason being given?

8 A. Well, I don't remember reading
9 any reason being given. I don't -- I'm not
10 sure whether there was a reason.

11 Q. Did you -- I believe you told
12 us earlier that you only reviewed about 20
13 pages of Demetra Ashley's deposition.

14 Do you recall saying that this
15 morning?

16 A. Yeah, I think I might have
17 corrected it and said or a few more, but I
18 don't recall reading it all the way to
19 conclusion.

20 Q. Why not? Why didn't you read
21 it all the way to -- what was -- why did you
22 decide to stop reading that deposition after
23 20 or so pages?

24 A. Well, I think I said -- I
25 didn't say the definitive amount. I think I

1 corrected myself. I -- I don't want to say I
2 didn't see much value in it. I just --

3 Q. After 20 pages?

4 A. No, I read it a lot longer than
5 20 pages.

6 Q. Wait. Did you read it a lot
7 longer than 20 pages? Did you read 20 pages?
8 Did you read a little longer? Do you not
9 know?

10 A. I'm not exactly sure how long.
11 I know I didn't read it to conclusion. I
12 don't really have an explanation. I just was
13 in the middle of finalizing or working on my
14 report. I just didn't see -- I don't want to
15 say a lot of value in it because everything
16 has value, but I just -- I don't know why. I
17 just didn't complete reading it.

18 Q. So you didn't see her
19 discussion in the deposition about the fact
20 that these distributor initiative briefings
21 were stopped for a period of time and why?

22 A. I don't recall that in her --
23 that I read that in her deposition. If you
24 were just asking me to give a recollection, I
25 would think it was Mr. Prevoznik's, but I'm

1 not sure.

2 Q. Well, do you recall what
3 Mr. Prevoznik's explanation was, was that
4 they were stopped for a period of time
5 because of pending litigation?

6 Do you recall that?

7 A. I don't remember the
8 litigation. I thought maybe it said
9 investigations or some kind of pending
10 matter, but I don't remember that it was
11 litigation.

12 Q. Well, I'll represent to you
13 that he actually said litigation.

14 A. Okay.

15 Q. Does that seem appropriate to
16 you?

17 A. That they suspend them for
18 litigation purposes?

19 Q. Yeah. Yeah.

20 MR. FULLER: Object to form.

21 A. I don't know what the
22 litigation was, so I don't really have a
23 comment on that.

24 BY MR. NICHOLAS:

25 Q. Well --

1 A. I guess that's Mr. Prevoznik's
2 issue to comment on.

3 I'm not sure, under my
4 authorization from the DEA, if I even knew I
5 could comment on that.

6 Q. In your report -- and you can
7 turn to the pages if you want. Starting on
8 page 40, you make reference to five different
9 methodologies that address the issue of the
10 number of suspicious orders that were and
11 weren't reported in the Track 1
12 jurisdictions, correct?

13 A. I think I report dosage amounts
14 based on the methodologies.

15 Q. I'm sorry. I'm sorry. I
16 apologize. Dosage amounts.

17 So we're talking about the
18 number of -- however you want to describe it,
19 the number of pills or the number of dosage
20 amounts of pills that are going into these
21 jurisdictions over a period of time; is that
22 right?

23 A. Yes, based on that particular
24 methodology.

25 Q. Okay. Well, you say that

1 particular methodology. You used -- you
2 referenced five methodologies, correct?

3 A. Yes, sir.

4 Q. Okay. Did you figure out those
5 methodologies yourself, or did Mr. McCann do
6 that?

7 A. No, those are mine based on --

8 Q. These five methodologies are
9 yours?

10 A. Yes. Well, they are
11 methodologies that are mirroring suspicious
12 order systems that are utilized by one or
13 more companies in my report.

14 Q. Okay. So did you -- you put
15 these -- did you put these charts together
16 yourself?

17 A. No, I did not.

18 Q. Who put the charts together?

19 A. I -- I'm sorry.

20 Well, this is based on
21 McCann's -- Mr. McCann takes -- took my
22 methodology, and these were the results of
23 his application of my methodology to the
24 ARCOS data.

25 Q. I see.

1 So you -- you came up with
2 these five methodologies?

3 A. Yes, sir.

4 Q. Okay. And tell me -- tell me
5 why you chose these five methodologies. I
6 think you started to do it, but just go ahead
7 and explain it to me.

8 A. Well, because these are
9 methodologies that were used by one or more
10 companies in my report, during the time frame
11 of my report. Each one of these were not
12 invented by me, but they were actually used.

13 Q. Okay. Can you -- let's start
14 with the first one. Methodology A is maximum
15 monthly trailing six-month threshold.

16 Can you explain to me what you
17 were trying to express here?

18 A. Well, this is the Masters case
19 methodology.

20 Q. Okay.

21 A. Or I shouldn't say methodology.
22 This is their suspicious order system. So
23 it's a rolling six-month, and it looks for a
24 current month that exceeds the highest
25 previous amount in the six months.

1 Q. Okay. And so when you refer to
2 flagged orders, you've got -- you know, your
3 top column, it's a grid.

4 A. Yep.

5 Q. And from left to right, across
6 the top, first it's the name of the
7 distributor. Then it says: Flagged orders
8 of oxycodone (dosage units). Then it says:
9 Flagged orders of hydrocodone (dosage units).

REDACTED

REDACTED

7 Q. So are you saying -- well, what
8 are you saying when you express this? I
9 shouldn't say.

10 I mean, you're showing it.
11 What does it mean?

12 A. So the methodologies applied to
13 the distribution, once the suspicious order
14 is identified, the criteria I used is if
15 there was no due diligence to dispel the
16 suspicious order or it wasn't reported, then
17 every subsequent distribution would be a
18 suspicious order.

19 Q. Let me -- I hate this
20 expression, but I'm going to have to unpack
21 that.

22 So the criteria you used -- you
23 say once the suspicious order is identified?

24 A. By the company -- or by the
25 methodology, I'm sorry.

1 Q. I mean, that's my first source
2 of confusion is, are these suspicious orders
3 or are these what you are suggesting should
4 have been suspicious orders, that you're
5 basing this on?

6 A. Well, it's not suspicious --
7 MR. FULLER: Objection to form.

8 A. It's not suspicious orders.
9 It's dosage amounts that resulted from
10 suspicious orders. So the methodology -- my
11 understanding of what Mr. McCann did -- and I
12 don't want to speak for him.

13 BY MR. NICHOLAS:

14 Q. Okay.

15 A. -- is he looks at the
16 distribution, the ARCOS data for the
17 distribution for AmerisourceBergen drug
18 company, he applies the methodology, and if
19 there are no suspicious orders, it just runs
20 along the distribution.

21 At some point, if there's a
22 month that exceeds the greatest month in the
23 previous six-month, that stops and it's a
24 suspicious order. So at that point, if there
25 was a due diligence to dispel that suspicious

1 order, if I could find that in my
2 investigation, then it would continue on.

3 If there was no due diligence
4 and, as my report details, there wasn't
5 during the early time periods -- during most
6 of the time period there was no due diligence
7 to dispel suspicious orders, so every
8 subsequent order would become a suspicious
9 order.

10 Q. On what basis are you saying
11 that there was no due diligence done to --
12 with regard to flagged orders? What is your
13 basis for saying that?

14 A. There were review of records
15 submitted on discovery.

16 Q. Records for --

17 A. Now, let me -- can I correct
18 this?

19 Q. Yeah.

20 A. I don't want to say none
21 whatsoever. I believe that probably there
22 may have been some individual instances of
23 due diligence, but in a general statement, at
24 a systematic level, there was insufficient
25 due diligence. Or none.

1 Q. And what is your basis for that
2 statement?

3 A. Reviewing records.

4 Q. Reviewing records provided to
5 you by the plaintiffs?

6 A. By the drug companies under
7 discovery.

8 Q. You only had access to the
9 records that the drug companies supplied in
10 discovery to the extent they were sent to you
11 by the plaintiffs' lawyers that were
12 retaining you, correct?

13 MR. FULLER: Object to form.

14 A. I'm not sure how to answer that
15 because I guess I hope I got all the records.

16 Now, I'm not indicating that I
17 looked at every one, but I looked at enough
18 to draw a conclusion or an opinion that there
19 was insufficient due diligence.

20 BY MR. NICHOLAS:

21 Q. Well, if you weren't sent
22 records that are -- that exist, how do you
23 know how many of the -- how many -- how do
24 you know whether you looked at a few, some,
25 most or all of the records? How do you know?

1 A. I think that's kind of a
2 hypothetical question.

3 Q. No, it's not hypothetical. You
4 told me that -- you told me that you obtained
5 records from plaintiffs' counsel, correct?

6 A. And it's my belief that I had
7 access to all the records. Now, there's no
8 way that I would know if that occurred or
9 not. That's -- I'm hopeful, as their expert
10 opinion, that I had access to all of the
11 records.

12 I can't affirmatively say that
13 they gave me every record. I -- that's why
14 it's kind of a hypothetical.

15 Q. Well, right now it is a
16 hypothetical because we really have no idea
17 what records you were provided, what records
18 you were provided and what you weren't
19 because I think you told us that you didn't
20 write down all the records that were provided
21 to you.

22 A. Well, I would say that in
23 regards to this matter, I reviewed sufficient
24 due diligence records to draw -- to make my
25 opinion.

1 Q. Now, sticking with that for a
2 minute, just because you did not review due
3 diligence records from 2010, 2011, 2012 --
4 let's assume you didn't see due diligence
5 records or as many as you would have liked.
6 That doesn't mean that the due diligence
7 wasn't done, does it?

8 A. Well, as far as the DEA is
9 concerned, if there's no documentation or
10 record of it, a due diligence file, my
11 opinion would be based on that that doesn't
12 exist.

13 Q. Well, we've already discussed
14 the fact that there was no requirement in the
15 regulations as to the retention of due
16 diligence records --

17 MR. FULLER: Object to form.

18 BY MR. NICHOLAS:

19 Q. -- for any period of time,
20 right?

21 MR. FULLER: Object to form.

22 That's not the witness's testimony.

23 A. So I don't think that's exactly
24 what my statement was. I think my statement
25 was is that it wasn't contained as a required

1 record in the recordkeeping section of the
2 CFR.

3 BY MR. NICHOLAS:

4 Q. Yeah.

5 A. But it was of my opinion that
6 it's covered under the maintenance of
7 effective controls, and it would be my
8 opinion as -- with my experience and my
9 training and my knowledge, is that it should
10 be kept forever. It's a historical record,
11 and it should be kept by the registrant much
12 greater than two years.

13 Q. Now, you keep saying that the
14 requirement to maintain records is contained
15 in the section pertaining to maintenance of
16 effective controls, but just so the record is
17 clear, there's nothing in the section on the
18 maintenance of effective controls that makes
19 any reference to records, correct?

20 A. Well, I --

21 MR. FULLER: Form.

22 A. I think within the statements,
23 that's what that statement means.

24 BY MR. NICHOLAS:

25 Q. Means. But I'm asking whether

1 there's any actual written reference to
2 records or the retention of records in that
3 section?

4 A. Well, so in the maintenance of
5 effective controls?

6 Q. Yeah.

7 A. It doesn't specifically say
8 that, if that's what you're...

9 Q. Okay. Okay. Now -- so just --
10 we'll break for lunch, but just so I
11 understand, the methodologies that -- the
12 five methodologies described here were
13 selected -- were identified or selected by
14 you. Is that -- based on what you saw the
15 various companies had done over the years; is
16 that correct?

17 A. Yes, sir.

18 Q. And you provided just those
19 methodologies, the concepts, to Mr. McCann
20 and he plugged in the numbers; is that
21 correct?

22 A. Yes, but just as a
23 clarification, I personally didn't discuss
24 that with Mr. McCann. I discussed it with
25 counsel and then counsel relayed that to

1 Mr. McCann. And then it didn't come -- I
2 didn't have -- I've never had a personal
3 discussion with Mr. McCann about this. It
4 was relayed through attorneys and back.

5 Q. Okay. Now, there are five
6 methodologies here. Which one are you
7 endorsing?

8 A. None.

9 Q. You don't endorse any of them?

10 A. No, sir.

11 Q. Okay.

12 A. I used these methodologies
13 because they were used by the industry. So I
14 didn't want to impose a methodology that
15 wasn't, you know, recognized or utilized by
16 one or multiple distributors.

17 MR. NICHOLAS: Okay. Okay.

18 Let's take a break.

19 THE VIDEOGRAPHER: Going off
20 the record at 12:46 p.m.

21 (Recess taken, 12:46 p.m. to
22 1:30 p.m.)

23 THE VIDEOGRAPHER: We're back
24 on the record at 1:30 p.m.

25 MR. FULLER: Counsel, I think

1 Mr. Rafalski had something he wanted
2 to clarify related to his last -- or
3 your last question.

4 THE WITNESS: I don't know if
5 it was the last or one of the last. I
6 apologize, I think I was more focused
7 on going to the bathroom than the
8 question.

9 But you asked if I endorsed a
10 methodology.

11 MR. NICHOLAS: Uh-huh.

12 THE WITNESS: I guess I
13 understood -- or I believed that
14 question was asking if I endorsed a
15 methodology as a suspicious order
16 system or whether I endorsed it as one
17 of my methodologies.

18 So I'm -- I answered it because
19 I thought you thought I would endorse
20 it as a suspicious order system, so
21 I'm not sure how you asked that
22 question. So I --

23 BY MR. NICHOLAS:

24 Q. Okay. No, I appreciate that.
25 I'm glad you did the clarification.

1 So you don't -- so --

2 A. I didn't want to say that I
3 didn't endorse my own methodology.

4 Q. Okay. So of these five, which
5 methodology, if any, do you favor or endorse
6 for purposes of the analysis you're doing?

7 A. That would be the Masters.

8 Q. Okay.

9 MR. FULLER: Which is the first
10 one, right?

11 THE WITNESS: And that's --
12 yes, that's methodology one.

13 A. And essentially because it has
14 been reviewed and an order issued -- or an
15 opinion issued by the D.C. court.

16 BY MR. NICHOLAS:

17 Q. Now, just work with me here,
18 because I want to make sure I'm understanding
19 what you're saying and also what you're not
20 saying, okay?

21 Let's just look at the column
22 for -- I'm on page 41.

23 A. Okay.

24 Q. The column for, I don't know,
25 flagged orders of oxycodone dosage units, and

1 you go right down each company, all right.
2 You've got one, two, three, four, five
3 companies, and in the case of each one,
4 you've got a parenthetical that says that
5 somewhere between -- that identifies
6 somewhere between 86.5% and 95.3% of total
7 dosage units, okay?

8 A. Yes, sir.

9 Q. All right. And that means
10 what? Is that the number of dosage units
11 that in your opinion should not have been
12 shipped?

13 A. Well, in my report, if we -- I
14 actually make a statement in regards to that
15 on page 46.

16 Q. Okay.

17 A. So it starts after the
18 footnote 151: However, it is my opinion to a
19 reasonable degree of professional certainty
20 that applying the tests set forth in the
21 Masters Inc. and Drug Enforcement
22 Administration provides a reasonable estimate
23 and initial trigger on a first step to
24 identifying orders of unusual size.

25 Q. So are you saying that --

1 A. Well --

2 Q. -- this is the number of --

3 MR. FULLER: Well, go ahead and
4 finish your answer.

5 MR. NICHOLAS: Okay. I thought
6 you were done. Sorry.

7 A. So -- and I can read the rest
8 of the paragraph.

9 BY MR. NICHOLAS:

10 Q. Don't read. I'd rather you
11 just tell me just in words, in your words,
12 what -- you know, what is it you're trying to
13 convey here?

REDACTED

REDACTED

5 Now, that --

6 Q. Okay. All right. So my
7 question is -- all right. So let me try
8 this.

9 Are you suggesting in your
10 report that more orders should have been
11 reported as suspicious?

12 A. Well, I don't think it suggests
13 that. I'll restate it again.

14 So when the system triggers a
15 suspicious order, it doesn't reset to the
16 next order to be a suspicious order. So how
17 I interpret the regulations and how my
18 training is and how the Masters ruling and
19 some of the documents I've read in regards
20 from McKesson and Cardinal and Prevoznik's
21 deposition testimony, is that once a
22 suspicious order is identified by registrant,
23 it should be stopped and there should be a
24 due diligence to dispel whether or not that
25 suspicious order is in fact suspicious.

1 If the registrant takes no
2 action and just continues to ship subsequent
3 orders in that order, then they're all
4 suspicious orders.

5 Now, my last paragraph kind of
6 sums up that this is how I applied this, and,
7 you know, it's in regards to how the court
8 would or would not accept it and there would
9 be other methodologies. So that's how I
10 interpret it.

11 Q. You know, on this subject I
12 think -- well, are you able to tell us -- are
13 you able to -- well, let's see.

14 Let's say an order is
15 identified by a distributor as suspicious,
16 okay?

17 A. Yes, sir.

18 Q. And it's reported to the DEA as
19 suspicious.

20 A. Yes, sir.

21 Q. Okay. You agree that that
22 doesn't necessarily mean that that order --
23 that the pills associated with that order are
24 going to be diverted, right?

25 A. No, I think that's exactly what

1 it means.

2 Q. You think every time that an
3 order is reported as suspicious that those
4 pills turn out to be diverted?

5 A. I don't know that I could draw
6 that conclusion, but I --

7 Q. That's the conclusion I'm
8 asking you about.

9 A. Well, I wouldn't draw that
10 conclusion. The only conclusion I would draw
11 is that if a registrant is adhering to the
12 law and the regulations and has a suspicious
13 order system in place and their system
14 identifies that, I would hope that they
15 believe that they're reporting to the DEA
16 what they believe to be a suspicious order.

17 Q. I'm asking you a completely
18 different question, okay?

19 My question to you is: When an
20 order was reported as suspicious -- strike
21 that. Strike that, because I -- I asked a
22 confusing question.

23 I think what you're saying is
24 that there are -- but tell me if I'm wrong --
25 is that more orders should have been reported

1 as suspicious than were reported; is that
2 right?

3 A. No.

4 Q. Okay. So you think that the
5 appropriate number of orders --

6 A. I --

7 Q. -- into Track 1 and Track 2
8 jurisdictions that were reported as
9 suspicious was indeed appropriate, that the
10 right number was reported?

11 A. This methodology doesn't look
12 at it that way because there was no due
13 diligence so --

14 Q. Hold on. Let me stop you
15 there.

16 MR. FULLER: Well, object --

17 MR. NICHOLAS: Go ahead. No,
18 I'm sorry. You're right. You're
19 right. Go ahead.

20 A. Because there was no due
21 diligence. So the methodology is not applied
22 to identify future orders that are
23 suspicious, because when you don't dispel the
24 suspicion or the potential that it's going to
25 be diverted and you can clear it to say that

1 it's not going to be diverted, then every
2 subsequent order, in my -- in the way I've
3 applied this, would be a suspicious order
4 based on the policies and the guidance and my
5 experience with the DEA.

6 BY MR. NICHOLAS:

7 Q. So your entire analysis here
8 rests on the premise that no due diligence
9 was done on the orders that you're reporting
10 on here; is that right?

11 MR. FULLER: Object to form,
12 misstates his prior testimony.

13 A. No -- either no or insufficient
14 due diligence.

15 BY MR. NICHOLAS:

REDACTED

REDACTED

5 So it's -- you know, the
6 critical thing I think that we -- that, you
7 know, that we are having trouble
8 communicating --

9 Q. We're definitely not
10 communicating right now and I'm sure I'm
11 not understanding this.

12 A. -- back and forth is the
13 concept that when you don't do due diligence,
14 that that makes every subsequent order a
15 suspicious order.

16 Now --

17 Q. That's what you're saying?

18 A. Yes, if there is insufficient
19 or there's incomplete or there's no due
20 diligence.

21 Now, that's a methodology
22 that's, I think, up to the court whether or
23 not to accept, but that's -- so it's just as
24 long as you understand clearly on how I had
25 this methodology applied.

1 Q. So again, your methodology
2 rests on your --

3 A. Opinion.

4 Q. -- conclusion or opinion that
5 either no due diligence was applied or
6 insufficient due diligence was applied -- you
7 know, was utilized by any of these companies,
8 and that results in these large numbers of
9 dosage units and these percentages; is that
10 right?

11 A. Yes, sir. My -- I'd like to
12 add to that as my final -- the final in
13 the -- on again, on 46, and this will maybe
14 be a clarification of what I said earlier,
15 the last sentence of the first paragraph: I
16 say this understanding that the litigation
17 will be advanced by selecting a methodology
18 qualifying a volume of pills that entered the
19 CT1 jurisdictions unlawfully and providing
20 this data to an economist to measure harm
21 caused by this volume.

22 Q. Yeah. You say in the -- the
23 first sentence of that paragraph says: I've
24 been asked to identify the number of opioid
25 pills that entered Cuyahoga and Summit

1 Counties unlawfully. This is an impossible
2 task due to the defendants' failure to comply
3 with their federal, statutory and regulatory
4 requirements.

5 What failure are you referring
6 to? The failure to do due diligence?

7 A. That would be the main
8 obligation under the law, the maintenance of
9 effective controls would be to do due
10 diligence, or I guess as you have asked me
11 earlier, if due diligence occurred and
12 there's no documentation, there's no way for
13 me to know that it ever existed, nor is it
14 for the registrant to know if an order came
15 in two days later. There's no historical
16 record of it.

17 Q. So part of the assumption
18 here -- because you're going back in this
19 methodology to 1996, right?

20 A. Yes, sir.

21 Q. And so what you're saying is
22 that if you don't see documentation of due
23 diligence from 1996 or 1997, say, then you're
24 concluding for purposes of this report that
25 the due diligence didn't occur?

1 A. That's not what I respond --
2 how I answered the question just a couple of
3 questions ago.

4 So there could have been at
5 some point for each of these companies where
6 they designed or developed a system where
7 they met the regulatory and the legal
8 requirements. They had due diligence. They
9 had an effective system, and they began to
10 identify suspicious orders, and they -- they
11 did a -- more than a cursory approval and
12 they did due diligence. So that would stop
13 the count.

14 And then the methodology would
15 be applied again, and every one that was
16 identified, if there was effective due
17 diligence, it wouldn't be counted as a
18 distribution to the CT1.

19 Q. Did you stop the count at any
20 point in this analysis?

21 A. No, sir.

22 Q. And that's because you assumed
23 that there was no due diligence done at any
24 point from 1996 to your end date here --

25 MR. FULLER: Object --

1 BY MR. NICHOLAS:

2 Q. -- at least for the purposes of
3 your numbers?

4 MR. FULLER: Object to form.

5 A. It's not an assumption. It's
6 based on my review of records and depositions
7 and documents that I couldn't find a time
8 period where I believed there was sufficient
9 due diligence -- well, there was actually a
10 complete failure.

11 There was the failure to stop
12 suspicious orders, there was ineffective
13 suspicious order systems, but in regards to
14 what caused these large numbers, it was the
15 failure to have the maintenance of effective
16 controls to prevent diversion, which is the
17 act of the due diligence, the reviewing those
18 orders to approve them as was detailed in the
19 Masters opinion.

20 BY MR. NICHOLAS:

21 Q. Okay. Now, see if we can agree
22 on one thing here, which is this: There
23 could be an order of unusual size or
24 frequency or pattern that is shipped.
25 Whether it should have been or shouldn't have

1 been, we can put aside for another day.

2 Okay? Let's just say that there's an order
3 of unusual size, frequency, pattern, that, in
4 fact, was shipped and it -- you can even
5 say -- and let's say it should have been
6 reported as a suspicious order, but it
7 shipped. All right?

8 Do you agree that even though
9 that order was shipped and even though you
10 say it shouldn't have been shipped, it
11 doesn't necessarily mean that the pills that
12 underlie that order are going to be diverted.
13 You don't know.

14 MR. FULLER: Object to form.

15 BY MR. NICHOLAS:

16 Q. Correct?

17 A. So I'll answer that question by
18 saying that if it's identified as suspicious
19 order by unusual size or unusual frequency or
20 deviating form -- you know, substantial
21 deviation from a pattern, so to me that puts
22 it as a probable, greater than 51% that it's
23 going to be diverted because it's been
24 identified.

25 So I can't draw the conclusion

1 that I don't know that it's going to be
2 diverted. I probably can't draw a definitive
3 statement that it is, but I'm going to say
4 that it's more probable because the system
5 identified it.

6 Q. So you got it at 51% above,
7 it's going to be diverted; is that what
8 you're telling me?

9 A. Well, that's the definition of
10 probable. If it's an effective suspicious
11 order system, I believe the percents would
12 rise much higher than that, but I guess that
13 depends on the effectiveness of the
14 suspicious order system.

15 Q. Where are you getting that
16 percent from? Where are you getting that
17 from, just your own --

18 A. What?

19 Q. The 51, the probable, where are
20 you getting that it's probable?

21 A. That's my belief of what
22 probable means.

23 Q. Okay. Other than your belief,
24 is it written down anywhere? Is there any
25 research on that? Is there any data on that?

1 Is this just -- just your belief?

2 A. Not that I can cite.

3 Q. Okay.

4 MR. FULLER: Vegas odds.

5 MR. NICHOLAS: Okay.

6 BY MR. NICHOLAS:

7 Q. Did you look at any individual
8 orders from any pharmacies in the Cuyahoga or
9 Summit Counties?

10 A. I looked at some DEA 222 forms,
11 but I believe my recollection, it was out of
12 maybe the Boston area, so I would say no.

13 Q. Okay.

14 A. No original records. I
15 reviewed no original records.

16 Q. You reviewed data that was in
17 the aggregate, right, totals? Correct?

18 A. No. I reviewed -- so just so
19 we're clear on, you know, what we're talking
20 about, so there's no confusion.

21 Q. Uh-huh.

22 A. So to me, in the DEA world, an
23 original record is the actual DEA order form,
24 the invoice or a CSOS electronic order form.
25 So that's what I would consider an original

1 record. Also provided to me, there's the
2 ARCOS data, which is not an original record,
3 and there were some electronic databases that
4 appeared to me to be an electronic
5 spreadsheet or an electronic format of orders
6 that distributors or registrants had
7 submitted as part of the discovery. But none
8 of those would be what I would consider an
9 original record.

10 Q. Can you identify a particular
11 order from a particular pharmacy that you
12 believe should have been reported as
13 suspicious?

14 A. Well, in my assignment to
15 create this and do the investigation to come
16 to this opinion, there wasn't a requirement
17 for me to actually find specific orders that
18 were suspicious.

19 First of all, it would require
20 the use of the suspicious order system of the
21 registrant, like what would be the criteria.
22 The -- and the thing I found in doing my
23 opinion is that probably the most critical
24 part of setting up a suspicious order system
25 is the due diligence or sometimes in the

1 industry they call it the onboarding, and
2 that's to establish what the criteria is. I
3 said earlier what the usual is.

4 And I found it difficult
5 because I didn't really find an adequate
6 effort to set up what actually would be a
7 usual or what would be an expected order. So
8 for me to go in and try to make that kind of
9 analysis wouldn't be possible.

10 Q. So sitting here today, you
11 can't identify a particular order from a
12 particular pharmacy that should have been
13 reported as suspicious that wasn't; is that
14 correct?

15 MR. FULLER: Form.

16 A. I don't know because I didn't
17 task myself to do that.

18 BY MR. NICHOLAS:

19 Q. Sitting here today, can you do
20 it? I know you didn't -- I know it wasn't
21 part of your job description here. That's
22 all I want to know is can you do it today?
23 Is it part of your report?

24 A. Well, actually, let me retract.
25 I think I did that and I think it's on

1 page 59 of my report. I think I used a
2 methodology. I believe it was the Cardinal
3 methodology, cage pickers, and I applied
4 their methodology to the orders and I believe
5 I came up with a total. Yes, it's on
6 page 59. So Cardinal had in place an
7 excessive orders system. At the beginning it
8 says: Cardinal Health Systems early 1990s to
9 2008 was also designed to identify individual
10 orders that appear to be excessive, on a
11 daily basis, and notify the DEA if possible
12 before the order is shipped.

13 Excessive orders are defined by
14 the following dosage limits. And these
15 limits, among many others, were posted in the
16 cage -- or the vault in the Cardinal
17 facility.

18 Q. What page are you on? I'm
19 sorry?

20 A. 59.

21 Q. Yeah, okay. All right. I'm
22 with you.

23 A. So I applied these amounts, and
24 I -- well, I requested Mr. McCann to apply
25 these amounts into the distribution records

1 for Cardinal, and the result of using these
2 amounts for Cuyahoga County was 1,000 --
3 166,869 orders of oxycodone and the
4 corresponding dosage amounts were 88,238,715.
5 Those numbers aren't dependent on due
6 diligence. Those would be the amount of
7 orders, if Cardinal would have used that
8 system and applied it to their distribution,
9 those were the number of orders that they
10 would have reported to the DEA, and that's
11 the corresponding dosage units. And they
12 reported none during that time period, using
13 this system.

14 Q. Have you identified a
15 particular order in the answer you just gave
16 me?

17 A. Yes, 166,869. I didn't ask
18 Mr. McCann to give me the list of each of the
19 orders, but each one of those would be a
20 specific order that should have been reported
21 based on the system the registrant had in
22 place.

23 MR. FULLER: Counsel, just for
24 my clarification. You're just wanting
25 him to pick out a specific date, a

1 specific order out of all those that
2 have been identified?

3 BY MR. NICHOLAS:

4 Q. I want to understand whether
5 your analysis involved review of specific
6 particular orders on particular days sent to
7 particular -- sent by particular pharmacies
8 to distributors. I think the answer to that
9 is, no, not that -- it's not that
10 controversial a question. I'm really just
11 trying to get a simple yes-or-no answer.

12 A. Well --

13 Q. Did you look at individual
14 orders that were sent to distributors,
15 individual ones?

16 MR. FULLER: Object to form.
17 Pharmacies don't send orders to
18 distributors.

19 MR. NICHOLAS: Okay.

20 MR. FULLER: Well, I mean y'all
21 chuckle. The question says for the
22 record --

23 A. I didn't look on an individual
24 basis --

25 MR. FULLER: Hold on. The

1 question says, for the record, sent by
2 particular pharmacies to distributors.
3 That's the question you asked.

4 Pharmacies don't send --

5 MR. NICHOLAS: What are you
6 yelling at me for? I don't --

7 (Simultaneous discussion
8 interrupted by the reporter.)

9 MR. NICHOLAS: Go ahead.

10 MR. FULLER: I'm sorry, I'm
11 just trying to make sure the record is
12 clear.

13 MR. NICHOLAS: So you were
14 starting to answer.

15 THE WITNESS: Sorry. Could you
16 ask the question again.

17 MR. NICHOLAS: Well, your
18 lawyer managed to interrupt, so I'll
19 have to do it again. Let's see.

20 BY MR. NICHOLAS:

21 Q. I want to understand whether
22 your analysis involved review of specific
23 particular orders on particular days, sent to
24 particular -- sent by particular pharmacies
25 to distributors.

1 A. My analysis to form this
2 opinion wasn't specific to looking at each
3 order by order.

4 MR. FULLER: Object to form.

5 BY MR. NICHOLAS:

6 Q. For how long does the DEA
7 retain suspicious order reports?

8 A. Just for clarification of your
9 question, you mean the ones that are
10 submitted to the DEA by registrant?

11 Q. Yes.

12 MR. FULLER: Object to form,
13 and I'm going to instruct you not to
14 answer if it is based on information
15 you gained while being an agent and
16 not otherwise known publicly.

17 THE WITNESS: I guess on the
18 advice of counsel, I won't answer.

19 BY MR. NICHOLAS:

20 Q. In your review of all of the
21 records in this case that you did review --
22 and I understand you didn't review all of
23 them, but in your review of everything that
24 you saw, can you tell me based on that for
25 how long the DEA retains suspicious order

1 reports?

2 A. No, I cannot answer that
3 question.

4 Q. In your review of all these
5 records in the case, did you see any
6 instances of the DEA retaining any suspicious
7 order reports?

8 A. Yes. And my answer would be in
9 regards to my experience and knowledge, that
10 they're submitted electronically to DEA
11 headquarters and that there's, I'm sure, a
12 retention because they're available for
13 review.

14 Q. Are suspicious order reports
15 kept in a database by the DEA?

16 MR. FULLER: Objection. Same
17 instruction.

18 THE WITNESS: On advice of
19 counsel, I'm not going to answer that
20 question.

21 BY MR. NICHOLAS:

22 Q. So you're following your
23 counsel's instruction not to answer the
24 question of whether the DEA keeps suspicious
25 order reports on a database?

1 A. Well, I guess I'm going to not
2 answer, not based -- well, based on his
3 instruction, but it's because whether it's a
4 fact that's known by -- discoverable by just
5 the general public, and I -- I don't know, so
6 that kind of makes me not want to answer that
7 question because I don't know if a person
8 could just do some query from the general
9 public and obtain that answer.

10 Q. Well, I can tell you that this
11 deposition is designated as a confidential
12 process to which the public does not have
13 access and will not have access.

14 So with that assurance, can you
15 answer the question now as to whether -- the
16 simple question of whether the DEA keeps
17 suspicious order reports on a database?

18 MR. FULLER: No, Counsel, hold
19 on one second. The Touhy request has
20 no bearing on whether this is kept
21 confidential or not. Touhy
22 authorization says he can't testify to
23 anything that is not publicly known
24 and that he gained information during
25 his employment. Touhy authorization

1 allows him to testify based on the
2 facts reviewed and provided in this
3 case. So I'm still going to give him
4 the same instruction.

5 I'll be honest with you, I
6 don't know if it's public knowledge or
7 not, whether it's in a database or
8 not. It may be.

9 MR. NICHOLAS: Okay.

10 BY MR. NICHOLAS:

11 Q. Do you agree with the statement
12 made by Mr. Rannazzisi in his deposition that
13 99% of doctors prescribe opioids for
14 legitimate medical purposes?

15 A. I don't really have an opinion
16 or I really don't agree or disagree. I don't
17 have sufficient knowledge or experience or
18 reviewed any studies to be able to make a
19 comment on that.

20 Q. And do you agree with the
21 statement made by Mr. Patterson of the DEA,
22 formerly of the DEA, testifying in front of
23 Congress that 99.9% of doctors are trying to
24 do the right thing?

25 A. My answer --

1 MR. FULLER: Form.

2 Go ahead.

3 A. My answer would be the same.

4 I -- I don't know the pure math of that
5 question, but with over 1 million doctors,
6 99.9%, I'm not sure --

7 BY MR. NICHOLAS:

8 Q. Do you think the vast majority
9 of doctors are trying to do the right thing?

10 MR. FULLER: Form, scope.

11 MR. NICHOLAS: You can answer.

12 A. I would agree with that, that I
13 have no experience or knowledge that says,
14 you know, anything otherwise than the vast
15 majority. I guess we could maybe dispute
16 about what vast majority is, but...

17 BY MR. NICHOLAS:

18 Q. When do you believe the opioid
19 crisis began?

20 A. I would probably say the onset
21 would be the Internet pharmacy activity, the
22 illicit Internet pharmacy activity, I think
23 1999, around in that time period.

24 Q. Okay. When did you first
25 become aware that there was an opioid crisis?

1 Around that time?

2 A. No. Probably when I started my
3 employment with the DEA in the academy.

4 Q. 2004?

5 A. Yes, sir.

6 Q. Is there a point at which you
7 believe the opioid crisis became common
8 knowledge?

9 A. Yes.

10 Q. When is that?

11 A. Well, could I get a
12 clarification of what you believe is common
13 knowledge? Because what's common knowledge
14 to me is -- would you -- would your
15 definition of that be just if you were to
16 stop somebody and say what is an opioid?

17 Q. How about known to government
18 entities, cities, towns, counties, states.

19 MR. FULLER: Form.

20 A. Well, I think it's -- I think
21 it probably coincided with when the Internet
22 pharmacy illicit conduct got to --
23 identified. There was a study that was being
24 done and it was published and showed the
25 conduct of these Internet pharmacies and

1 distributions not pursuant to a prescription.

2 I think when that report was
3 published, I think, at least in regards to --
4 that's my belief, that that's when it pretty
5 much disclosed the scope of that activity.

6 BY MR. NICHOLAS:

7 Q. When was that study published,
8 roughly?

9 A. 2004-2005.

10 Q. Okay.

11 A. Now, just so I can clarify my
12 question, I think the DEA knew about it prior
13 to that.

14 Q. Yeah.

15 A. So just the clarification was
16 it would be just like when it really came out
17 and people should have a better awareness of
18 it, that would make -- okay?

19 Q. Okay. Yeah, I understand.

20 Now, each year the DEA sets a
21 quota as to the number of controlled
22 substances that are to be made available
23 nationwide; is that correct?

24 A. Yes, sir.

25 Q. Okay.

1 A. By law, I believe, and
2 regulation.

3 Q. And over time, during the --
4 during the past years, there was a period
5 when the number of opioid pills that were
6 reaching various communities in the country
7 was increasing, correct?

8 A. Yes, sir.

9 Q. Okay. In setting quotas each
10 year, did the DEA overestimate the medical
11 needs of the United States?

12 A. I don't really have sufficient
13 knowledge because I didn't work in the quota
14 section; it was done entirely in the
15 headquarters section. I really don't --
16 can't give an opinion on that particular
17 question.

18 I could maybe clarify that a
19 little bit.

20 Q. Yes, please.

21 A. Just my experience and
22 knowledge of just hearing about it and not
23 being directly related, that those -- those
24 quota amounts were approved based on
25 information that the DEA received from

1 manufacturers and distributors, and that was
2 some of the things they used to guide them in
3 setting the quota for the -- which is the
4 medical and scientific needs of the country.

5 But other than that, I don't
6 know how they evaluated that information.

7 Q. Well, does the DEA shoulder any
8 responsibility for setting the quotas? I
9 mean, does it have its own input, do its own
10 analysis, do its own work?

11 MR. FULLER: Object to form,
12 outside scope. And if it relates to
13 anything you gained knowledge on while
14 you were there that's not public
15 knowledge, your Touhy authorization
16 does not allow you to testify to it.

17 A. So -- I don't know, so my
18 answer -- I can't say I won't answer, because
19 I don't have any direct knowledge of that.

20 BY MR. NICHOLAS:

21 Q. Based on your personal
22 experience and years with the DEA, do you
23 believe that doctors went through a period of
24 time when they were overprescribing opioids?

25 A. So could you clarify what you

1 would consider to be overprescribing?

2 Because there's a couple of different ways I
3 think I could interpret that.

4 Q. Did doctors prescribe too many
5 opioid -- well, strike that. I'll try it
6 again.

7 A. Let me --

8 Q. Was there a period of time
9 when -- or do you believe doctors prescribed
10 more opioid pills than were medically
11 necessary for their patients?

12 MR. FULLER: Object to form.
13 He's not a medical doctor.

14 A. Well, my investigation into
15 some of them that I detailed as at least
16 bulleted in my report, would say that I would
17 ask -- answer that affirmatively because I
18 have some experience with doctors who did
19 issue illicit or diverted prescriptions.

20 So, you know, just in a general
21 answer would be yes. Now, I'm not going to
22 qualify that with how many or what, but
23 that's one of the essences of how diversion
24 occurs.

25 ///

1 BY MR. NICHOLAS:

2 Q. Are you able to tell -- well,
3 you wrote on your report on page 46, and we
4 read this already, that you had been asked to
5 identify the number of opioid pills that
6 entered Cuyahoga and Summit Counties
7 unlawfully, and then you went on to say it's
8 an impossible task, right? Page 46, first
9 full paragraph.

10 A. Yes.

11 Q. Okay. Are you able to tell us
12 the correct number of pills that should have
13 been shipped into Cuyahoga and Summit
14 Counties lawfully?

15 A. No, sir, I cannot provide that
16 information -- or did I calculate that
17 information or --

18 Q. Do you have any sense of it at
19 all?

20 A. Well, I'm supportive of my
21 opinion, and that's the failures by the
22 registrants during the time period was a
23 significant contribution to diversion and the
24 amount of pills. But to put a calculated
25 number, I can't do that. My methodology has

1 come to some conclusions based on, you know,
2 the due diligence factors.

3 Q. And in some regards, you'd
4 almost have to be a doctor to know an answer
5 to a question like that, right?

6 MR. FULLER: Form.

7 A. Well, I think that would be one
8 aspect, to be a doctor. But then, you know,
9 there's a lot of other factors that also
10 would be taken into consideration.

11 BY MR. NICHOLAS:

12 Q. But, I mean, you don't feel
13 qualified to look at a prescription for a
14 patient and know whether that prescription is
15 appropriate or not, correct?

16 A. Well --

17 MR. FULLER: Same objection.

18 A. I don't want to be
19 argumentative, but in my experience of doing
20 some cases, there have been instances where I
21 could look at a prescription, knowing how it
22 was written or the procedure that it was
23 used, and I could say that that was not a
24 legitimate prescription.

25 One example would be in one of

1 the cases I worked, patients would meet
2 doctors -- not patients. People would meet a
3 doctor in a parking lot, pay a hundred
4 dollars and get a prescription. So I don't
5 know that I would have to be a doctor to be
6 able to say that wasn't a legitimate
7 prescription.

8 BY MR. NICHOLAS:

9 Q. Fair enough. Sounds like
10 you're a little bit of a doctor, a little bit
11 of a lawyer and a little bit of a witness.

12 A. I just think that that doesn't
13 take either -- any of those quantifications
14 to say that there's something wrong with that
15 prescription.

16 Q. Okay. Just a little more, and
17 then I'll be done.

18 Now, you attended DEA basic
19 diversion investigator school in 2004; is
20 that right?

21 A. Yes, sir.

22 Q. Was that training at Quantico?

23 A. Yes, sir, it was -- I don't
24 want to say custodial training. It was a --
25 you actually stayed at the facility, 12-week

1 training.

2 Q. As part of your training, did
3 you go to AmerisourceBergen's Richmond
4 distribution center?

5 A. No, sir, I don't believe so.

6 Q. Okay. Are you aware of other
7 diversion investigator trainees who did so?

8 A. No, I'm not.

9 Q. Were you aware that
10 AmerisourceBergen in 2004 and 2005 worked
11 with the DEA to train DEA diversion
12 investigators?

13 A. I was not aware of that.

14 Q. Were you provided any documents
15 that would have shown you that?

16 A. I'm sure I was -- I think I was
17 provided access to all documents, but I don't
18 recall reviewing those particular documents.

19 Q. Okay. So to your knowledge,
20 the plaintiffs' lawyers didn't send you
21 documents pertaining to that; is that right?

22 A. I don't think I said that.
23 I -- I think I --

24 Q. I'm not saying you said it.
25 I'm asking you whether that's right, that to

1 your knowledge, the plaintiffs' lawyers
2 didn't send you those documents?

3 A. I can't answer affirmatively to
4 that because I believe I had access to all
5 the documents.

6 Q. Access to all the documents,
7 but I'm talking about what was actually sent
8 to you.

9 A. I think they were all -- in
10 some form or another, electronically, or I
11 think I had access to all the documents.

12 I guess just so I understand
13 the question, no one physically gave it to me
14 or said here is the document, but I don't
15 think that -- I think somewhere in all of the
16 production that they gave to me, that that
17 document could exist.

18 Q. Okay. So --

19 A. I hope that makes sense.

20 Q. It makes sense, but I guess now
21 I need to understand. So if you had
22 access -- if you think -- you don't know, but
23 you think maybe you had access to all the
24 documents in the case?

25 MR. FULLER: Form.

1 A. I believe I did. I don't think
2 there were any documents withheld from me.

3 BY MR. NICHOLAS:

4 Q. But you don't know one way or
5 the other, right?

6 A. Yeah, I think we discussed that
7 before lunch.

8 Q. We went over this, yeah.

9 A. There's no way that anyone
10 really knows --

11 Q. Right.

12 A. -- if -- that everything was
13 turned over. My belief is that it was.

14 Q. Okay. And -- but in all those
15 millions and millions of documents, you would
16 need someone to point you in the direction of
17 what to look at as opposed to what you don't
18 need to look at, right?

19 A. That's correct.

20 Q. Okay.

21 A. And in my earlier testimony, I
22 think I was clear that I didn't look
23 individually at every document. There were
24 people that assisted me in looking at
25 documents and guiding me and directing me to

1 certain documents, so it would be, I guess,
2 maybe in a lifetime, physically -- I don't
3 even know if it would have been a lifetime to
4 look at 50 million documents, but there had
5 to be some system to be able to look -- to
6 help me form my opinion to look at relevant
7 documents.

8 Q. Yeah. And that system was the
9 plaintiffs' lawyers directing you toward the
10 documents that they wanted you to look at?

11 MR. FULLER: Object to form.

12 BY MR. NICHOLAS:

13 Q. What other system was there?

14 A. Well, could you say the
15 question one more time.

16 Q. The system by which you wound
17 up reviewing some documents and not others
18 was dependent on the plaintiffs' lawyers
19 providing -- you know, directing you to the
20 documents that they believed you should look
21 at, right?

22 MR. FULLER: Object to form.

23 A. That's not a correct statement.

24 MR. FULLER: Contradicts his
25 earlier testimony.

1 BY MR. NICHOLAS:

2 Q. Okay.

3 A. I believe -- well, I don't
4 believe. What I did is I directed people to
5 look for me on my behalf, and I gave them the
6 types of documents and the types of
7 information I would need to form my opinion.

8 It wasn't that only -- so if I
9 understand your question, you are trying to
10 say that they only funneled to me certain
11 documents to form my opinion, and I directed
12 them to look for documents in certain areas
13 to meet my objective to give an opinion.

14 Q. Okay. And after you directed
15 them to look for those documents and provide
16 them, you were dependent on them to point to
17 the documents that you would ask for, right?

18 A. In some cases, yes, sir, or I
19 would try to look for them and find them
20 myself.

21 Q. Right. But in the instances
22 where when you were asking them to, like,
23 find the documents and send them to you, you
24 were necessarily dependent on them -- you
25 were relying on whatever they did send you as

1 the stuff that you had asked for, correct?

2 A. Just so -- and I'm going to
3 answer, but just so I can clarify my answer.
4 So if I said I would have wanted to see all
5 suspicious orders policy for a certain
6 company, it was my belief that somebody
7 looked and helped me locate those documents
8 and sent them to me.

9 Q. Okay. I understand.

10 So let's go back to 2004-2005.

11 (Whereupon, Deposition Exhibit
12 Rafalski-7, 10/25/04 CSRA Memo
13 w/Attachment(s), ABDCMDL00315829 -
14 ABDCMDL00315861, was marked for
15 identification.)

16 BY MR. NICHOLAS:

17 Q. This will be marked as
18 Exhibit 7.

19 A. Before I look at this, can I
20 make just a clarification?

21 Q. Uh-huh.

22 A. So during my training in 2004,
23 I went to the only facility -- we had a
24 couple of offsite visits to registrants, and
25 it's my belief that I think it was some kind

1 of a cough syrup manufacturer, but I just
2 wanted to make that clarification. I don't
3 think it was an AmerisourceBergen facility.

4 Q. All right. Can you look at
5 what has been marked as Exhibit 3 -- I'm
6 sorry, Exhibit 7.

7 A. Yes, sir.

REDACTED

REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED

16 Q. Well, we can agree on that.

17 Can we agree that it's
18 something -- that working with the DEA in
19 this fashion is something that
20 AmerisourceBergen should be proud of?

21 A. I think the DEA should be proud
22 of it too.

23 Q. I agree with that.

24 Can we agree that it's also
25 something that AmerisourceBergen should be

1 proud of?

2 A. Sure.

3 Q. Okay.

4 MR. NICHOLAS: Just give me 30
5 seconds or maybe one minute, see if I
6 have any other questions.

7 THE WITNESS: I'm not going to
8 hold you to that.

9 MR. NICHOLAS: The bad news for
10 you is that I'm not the only person
11 asking you questions today.

12 THE WITNESS: I'm sure not
13 everyone came here to watch you and I
14 discuss these matters, so I don't find
15 that surprising.

16 MR. NICHOLAS: Okay. Can we go
17 off for one minute? I'm going to be
18 very fast here.

19 THE VIDEOGRAPHER: Going off
20 the record, 2:34 p.m.

21 (Recess taken, 2:34 p.m. to
22 2:35 p.m.)

23 THE VIDEOGRAPHER: Back on
24 record, 2:35 p.m.

25 ///

1 BY MR. NICHOLAS:

REDACTED



REDACTED



REDACTED



REDACTED

13 Q. Well, there was some testimony
14 in Steve Mays' deposition about just this
15 subject, but as you've already told us, you
16 didn't read Mr. Mays' deposition, correct?

17 A. I don't recall reading it, no,
18 sir.

19 Q. Okay. Well, let's just talk
20 about that conference for a minute. The
21 Diversion Control Division of the
22 U.S. Department of Justice I believe
23 sponsored a conference with the
24 pharmaceutical industry -- it was called a
25 pharmaceutical industry conference -- in

1 September of 2007 in Houston.

2 Are you familiar with that?

3 Did you attend it, I should say?

4 A. I did not attend it. I'm
5 familiar that the conference occurred. That
6 came up in one of my other cases that I
7 investigated.

8 Q. Okay. And were you aware that
9 at that conference in September of 2007 in
10 Houston, Texas, Mike Mapes from the DEA and
11 Chris Zimmerman presented to the entire
12 industry on suspicious order monitoring
13 programs? Are you aware of that?

14 A. Just for clarification, I'm
15 aware that the industry training occurred and
16 that there was the discussion or there was
17 some presentation on it. I don't know the
18 extent of the presentation, but I know there
19 was some presentation in regards to
20 responsibilities in regards to suspicious
21 order systems.

22 Q. Are you aware that as part of
23 the presentation, Mr. Zimmerman from
24 AmerisourceBergen talked about ABDC's
25 program, new suspicious order monitoring

1 program or enhanced program to the entire
2 industry?

3 A. I believe that somewhere I had
4 reviewed -- or I don't know if it was my
5 previous employment experience or if it was
6 something I reviewed as part of my opinion,
7 but I was aware that it occurred.

8 Q. So in 2007 at a DEA-sponsored
9 conference, Mr. Zimmerman from
10 AmerisourceBergen was on stage with Mr. Mapes
11 presenting a description of
12 AmerisourceBergen's suspicious order
13 monitoring program to the entire invited
14 industry group, correct?

15 A. I don't have any information to
16 disagree or agree with you, so -- I don't
17 know that they stood on stage together. I
18 wasn't there. So if that's how you represent
19 it, I don't have any knowledge to disagree,
20 but...

21 MR. NICHOLAS: Okay. Let's
22 mark one more exhibit.

23 (Whereupon, Deposition Exhibit
24 Rafalski-9, 9/11-12/07 Meeting Agenda,
25 DEA Diversion Control Division

1 [No Bates], was marked for
2 identification.)

3 BY MR. NICHOLAS:

4 Q. Exhibit 9. This document,
5 Exhibit 9, Mr. Rafalski, is a brochure, I
6 guess, or a publication -- I don't know what
7 you want to call it -- sent around -- or
8 describing the upcoming -- what is then an
9 upcoming pharmaceutical industry conference.
10 It's the one we've been talking about. It
11 took place on September 11th and 12th, 2007
12 in Houston, Texas.

13 Do you see that?

14 A. I do.

15 Q. And it's got like a one, two --
16 it's got a two-day agenda, Tuesday and
17 Wednesday, the 11th and the 12th?

18 A. Yes, sir.

19 Q. And there is a section on
20 suspicious orders on the agenda on page 1 --
21 you know, on day one.

22 And if you turn to the second
23 page of this document, you can see the
24 description about the suspicious orders.

25 Do you see that?

1 A. Yep.

2 Q. Okay.

3 A. Yes, sir, about halfway down.

4 Q. Yeah. And basically, this
5 description just -- this blurb describes --
6 you know what, this makes it pretty clear
7 that this is a report of what happened at the
8 conference. It was after the fact.

9 Because it describes how
10 Mr. Mapes, the chief DEA regulatory section,
11 and Chris Zimmerman, vice president,
12 corporate security and regulatory affairs,
13 AmerisourceBergen, updated, past tense,
14 attendees on when suspicious order reports
15 should be submitted to authorities, and then
16 it goes on.

17 So does this document provide
18 you a little more comfort that what I'm
19 representing to you about the fact that
20 Mr. Mapes and Mr. Zimmerman made a joint
21 presentation to the group, the entire group
22 is, in fact, true?

23 A. It does. And it also jogs my
24 memory. There was a particular slide that
25 occurred during this conference in regards to

1 suspicious orders, and it was whether or not
2 the shipping requirement -- it wasn't called
3 the shipping requirement, but this particular
4 slide had language similar to the 2006
5 Rannazzisi memo, and that was once you
6 identify a suspicious order and continue to
7 ship the suspicious order without dispelling
8 the suspicion, it would be attributed to
9 diversion.

10 And I remember that slide. It
11 came up in a different investigation. So way
12 back at this time when this occurred, right
13 after, I think -- and I don't remember
14 exactly what year.

15 I think 2009 or '10, it -- this
16 came to my attention and there was a lot of
17 discussion about that -- the meaning of that
18 particular slide because there wasn't a
19 language where even back then the industry
20 was saying that DEA should just say stop
21 shipping an order, but what they would say is
22 if you failed to stop, it was a failure to
23 have effective controls against diversion.

24 Q. So it was kind of confusing to
25 the industry?

1 A. Well, I don't know if it was
2 confusing to the industry. It's the same
3 thing I've been saying all along. If you
4 report a suspicious order, then ship it --

5 Q. Well, they had a slide about
6 it. I guess somebody thought it was worth
7 showing people because they needed a slide
8 because it was perhaps not as clear as you're
9 saying it was.

10 A. No, I think it was stating the
11 same thing that Mr. Rannazzisi stated. So
12 why I remember it is in the course of how it
13 was used in this case, someone alleged it had
14 a different meaning. So we had the same
15 discussion back then about whether it meant
16 to stop a shipment or not.

17 Q. So you're saying this jogged
18 your memory. Like -- wait, though, does that
19 mean that you were at this presentation?

20 A. No.

21 MR. FULLER: Form.

22 BY MR. NICHOLAS:

23 Q. Oh, you just saw the slide
24 later --

25 MR. FULLER: Form.

1 BY MR. NICHOLAS:

2 Q. -- or something?

3 MR. FULLER: Form to the prior
4 three questions. Y'all just give me a
5 little bit of a pause if you don't
6 mind.

7 THE WITNESS: Yes, sir.

8 A. It jogged --

9 BY MR. NICHOLAS:

10 Q. You weren't at this --

11 A. I was not.

12 Q. Okay. So let's get back to the
13 question I was asking about. I appreciate
14 the detour there, but what I'm really wanting
15 to know is whether this provides you -- and I
16 think you answered yes -- provides you with
17 some comfort that my telling you that this
18 presentation occurred and that Mr. Mapes and
19 Mr. Zimmerman jointly presented to the entire
20 industry --

21 A. I could draw that conclusion by
22 reading these two paragraphs.

23 Q. Okay. Give me one more minute,
24 and I believe I'm going to --

25 MR. FULLER: That's what you

1 said last time.

2 MR. NICHOLAS: I know. Yeah,
3 I'm one of those guys, you know. All
4 lawyers are the same.

5 MS. QUEZON: But it probably
6 has been an hour if you want to take
7 five minutes.

8 MR. NICHOLAS: Has it been an
9 hour?

10 MR. FULLER: Yes.

11 MR. NICHOLAS: Let's take five
12 minutes. Good chance I'm done.

13 THE VIDEOGRAPHER: We're off
14 the record. The time is 2:51 p.m.

15 (Recess taken, 2:51 p.m. to
16 2:59 p.m.)

17 THE VIDEOGRAPHER: We're back
18 on the record at 2:59.

19 MR. NICHOLAS: Mr. Rafalski,
20 that's all the questions I have at
21 this time. I appreciate your time.
22 Thank you for answering my questions,
23 and in an incredible abundance of
24 caution, I'll reserve the remote right
25 to come back and ask you a few more

1 questions later, but I really think
2 that's unlikely. I don't think I'll
3 have any more.

4 THE WITNESS: Thank you very
5 much. Pleasure to meet you.

6 MR. NICHOLAS: Same.

7 EXAMINATION

8 BY MR. PYSER:

9 Q. Good afternoon, Mr. Rafalski.
10 My name is Steve Pyser. I'm going to be
11 asking you some questions today for Cardinal
12 Health, okay?

13 A. Okay.

14 Q. Have you ever visited any
15 Cardinal Health facility?

16 A. No, sir.

17 Q. Have you ever interviewed any
18 Cardinal Health employee?

19 A. No, sir.

20 Q. You stated earlier today that
21 in your work to date on this case, going back
22 about two years until today, including the
23 preparation of your report, you'd spent about
24 400 hours roughly on the case?

25 A. Roughly, yes, sir.

1 Q. Now, your report covers about a
2 dozen -- I think actually 13 different
3 defendants. Can you tell me approximately,
4 of that 400 hours, how much of that time did
5 you spend reviewing documents and depositions
6 related to Cardinal Health?

7 MR. FULLER: Form.

8 A. It's difficult for me to
9 answer, to just give you a specific number of
10 hours. I could say significant, but I know
11 that's not a full answer.

12 Over the last -- probably
13 beginning in the early fall, up until the day
14 I submitted my report, those were -- the
15 majority of hours in regards to the 400 were
16 spent during that time frame researching,
17 preparing the report, reading depositions and
18 looking at documents.

19 BY MR. PYSER:

20 Q. Maybe my question was unclear.

21 I understand that you spent a
22 large portion of the 400 hours looking at
23 documents and preparing your report.

24 A. Yes.

25 Q. I'm asking to break it down by

1 defendant a little bit.

2 A. Oh, okay.

3 Q. So if there's 13 defendants, is
4 it roughly spread evenly, divided by 13, you
5 get a rough approximation?

6 A. Well, I think I spent a little
7 more time on the distributors until I did
8 the -- instead of the manufacturers. I would
9 say I probably spent more time in totality
10 and individually in -- as far as just at the
11 distributors.

12 I would probably say pretty
13 equal except with Henry Schein, because
14 that's a smaller distributor and there was
15 less documents and less information to
16 review.

17 Q. So for each of the larger
18 distributors, we're talking something in the
19 range of 50 or 60 hours each; is that fair?

20 A. I guess that could be a
21 possible --

22 MR. FULLER: Object to form.

23 A. I guess it could be a possible
24 approximation.

25 BY MR. PYSER:

1 Q. Have you ever conducted a
2 cyclic investigation of a registrant?

3 A. Numerous times, yes, sir.

4 Q. In any of those investigations,
5 did you review a distributor who sent DEA
6 excessive purchase reports on a monthly
7 basis?

8 A. No, sir, never.

9 Q. Did you ever conduct a cyclic
10 investigation of Cardinal Health?

11 A. No, sir.

12 Q. In the course of your work
13 preparing for this case, did you review the
14 results of any cyclic investigations of
15 Cardinal Health?

16 A. So the way I'd like to answer
17 that is that I reviewed documents that --
18 communications intercompany that cyclic said
19 occurred or regulatory investigations, but I
20 didn't review the actual documents of the DEA
21 or of the actual conducting of the
22 investigation. So I hope that answers your
23 question.

24 I know they occurred and I know
25 there were some documents where there was an

1 internal assessment of what the DEA did, but
2 I never reviewed like the actual DEA
3 investigations.

4 Q. In the documents you did review
5 of the cyclic investigations, did you ever
6 see an indication that DEA had stated that
7 Cardinal Health's practice of sending monthly
8 ingredient limit reports to DEA was improper?
9 Did you ever see that indicated?

10 A. No, sir.

11 Q. You state in your report that
12 Cardinal's ingredient limit report system,
13 this monthly report, was premised on guidance
14 from the 1998 DEA report; you call it the
15 Reno report.

16 Do you recall that?

17 A. Yes, but I don't say that. I
18 think I provide an opinion because I believe
19 some Cardinal representative said that.

20 Q. You're aware that Cardinal
21 Health had the same system in place before
22 the Reno report came out?

23 A. Yes, sir.

24 (Whereupon, Deposition Exhibit
25 Rafalski-10, 10/98 Report to the U.S.

1 Attorney General, CAH_HOUSE-002207 -
2 CAH_HOUSE-002298, was marked for
3 identification.)

4 BY MR. PYSER:

5 Q. I'm showing you a document
6 that's been marked as Exhibit 10. Is this
7 the Reno report that you refer to in your
8 report?

9 MR. FULLER: You provided us
10 copies.

11 MR. PYSER: As we go down
12 through the day, there will be less
13 copies from each person asking
14 questions.

15 A. Yes, sir.

16 MR. FULLER: Now I don't feel
17 so bad that I didn't always comply
18 with the protocol.

19 BY MR. PYSER:

20 Q. Okay. If you turn with me
21 to -- using the pages in the bottom right,
22 the Bates pages, there's a page
23 CAH_HOUSE-002230.

24 A. Okay.

25 Q. Now, you had stated in your

1 report that the suspicious order monitoring
2 system recommended in this Reno report from
3 1998 was for List 1 chemicals. Do you recall
4 that conclusion or opinion?

5 A. Yes. Yes, sir.

6 Q. I want to direct you to the
7 actual report at Bates page 2230. Under B1,
8 Wholesaler Distributors, it states that those
9 in the wholesale drug distribution supply
10 chain who are able use the DEA-approved
11 suspicious order monitoring system in use by
12 wholesale drug distributors for controlled
13 substances.

14 Do you see that statement?

15 A. Yes, sir.

16 Q. So at the time in 1998, you
17 agree with me that there was a DEA-approved
18 suspicious order monitoring system in use by
19 wholesale drug distributors for controlled
20 substances?

21 A. No, sir. I agree that that's
22 what this statement says, but this is a task
23 force combined of industry members and there
24 were some DEA officials on there, one -- one
25 diversion investigator or someone from the

1 diversion unit. And so I'm not in
2 agreement -- and I see this is what the
3 document says -- that that's an accurate
4 statement.

5 Q. So even though it's on a page
6 with letterhead that says United States
7 Department of Justice, Drug Enforcement
8 Administration, you don't believe it's an
9 accurate statement?

10 A. I do not.

11 Q. This is six years before you
12 began your career at DEA, correct?

13 A. Yes, sir.

14 Q. So you weren't communicating
15 with anyone at DEA about this task force at
16 the time of the report in 1998, were you?

17 A. No, sir.

18 Q. It goes on to say --

19 A. Can I just clarify that?

20 Q. No.

21 A. Okay.

22 Q. It goes on to say --

23 MR. FULLER: Go ahead. You can
24 clarify your answer.

25 A. So just for clarification, and

1 I had testified earlier, but I understand
2 that each person is different. So at the
3 time that this statement was made in this
4 publication, which I don't believe it was
5 actually acted on. It was recommendations.
6 I just want to go back to the DEA manual was
7 in place in -- the 1996 DEA manual that would
8 be in conflict with that particular
9 statement.

10 BY MR. PYSER:

11 Q. This document was --

12 A. '98.

13 Q. -- published publicly in 1998,
14 correct?

15 A. Yes, sir.

16 Q. And are you aware if in 1998
17 anyone from DEA made a public statement that
18 said actually this report to the
19 U.S. Attorney General is wrong, it has an
20 incorrect statement? Are you aware of any
21 statement like that from DEA?

22 A. I am not aware of any statement
23 like that, no.

24 Q. The second paragraph on
25 page 2230 says: This is basically what is

1 done for Schedules II through V controlled
2 substances.

3 Do you see that?

4 A. Yes, sir.

5 Q. Okay. And what's being done
6 by -- what the report states is being done
7 for controlled substances on Schedules II
8 through V is a DEA-approved suspicious order
9 monitoring, correct?

10 A. As I stated earlier, I don't
11 agree with that.

12 Q. But it is what the report
13 states?

14 A. That is what the reports
15 states.

16 Q. And if you go a little bit
17 further in the report to Bates page 2247,
18 it's a document that again, at the top of the
19 document it says United States Department of
20 Justice, Drug Enforcement Administration,
21 Office of Diversion Control.

22 Do you see that?

23 A. Yes, sir.

24 Q. Okay. At the top it says:
25 Suspicious order reporting system of 1998 for

1 use in automated tracking systems.

2 Correct?

3 A. Yes, sir.

4 Q. And it begins by saying: The
5 current calculation being used for List 1
6 chemicals on Schedule II through V controlled
7 substances.

8 You see that statement?

9 A. I see that statement.

10 Q. Okay. So according to this
11 document, in 1998, six years before you
12 arrived at DEA, there was a calculation being
13 used for Schedule II through V controlled
14 substances?

15 A. Well, I'm going to repeat my
16 same answer. This was an advisory committee
17 that put this document together. I
18 acknowledge that it's on Department of
19 Justice letterhead, but I'm not aware of ever
20 seeing any approved DEA approval of any
21 system.

22 And I acknowledge that the
23 document says that, but later on it
24 specifically talks about Schedule II or
25 Schedule III through Vs that contain List 1

1 chemicals.

2 And when I read the document,
3 the totality of the document is about List 1
4 chemicals, and --

5 Q. Correct. The totality of the
6 document --

7 MR. FULLER: Let him finish his
8 answer, Counsel. Let him finish his
9 answer.

10 MR. PYSER: Well, he's not
11 answering my question.

12 MR. FULLER: Well, you may not
13 like the answer you're getting, but
14 he's going to finish his response.

15 Go ahead.

16 MR. PYSER: If he's wasting
17 time, I reserve my right to come back
18 for more time.

19 MR. FULLER: Great.

20 Go ahead, Mr. Rafalski.

21 A. And so the totality of this
22 document was in response to the new
23 methamphetamine act and the
24 pseudoephedrine -- making pseudoephedrine a
25 List 1 chemical. So, you know, to me, the

1 critical statement here is in 4, the note
2 under Section 4.

3 BY MR. PYSER:

4 Q. Sir. I'm not disagreeing with
5 you --

6 A. Okay.

7 Q. -- that this document was
8 prepared related to the Comprehensive
9 Methamphetamine Control Act of 1996, and what
10 it's saying is that they're going to
11 introduce procedures for List 1 chemicals
12 that are like those already in place for
13 controlled substances on Schedule II through
14 V. Isn't that what the document is saying?

15 MR. FULLER: Object to form.

16 A. Well, what the document says to
17 me is that if registrants, distributors have
18 electronic systems, that a registrant should
19 consider monitoring List 1 chemicals
20 utilizing that same electronic system.

21 BY MR. PYSER:

22 Q. And it actually speaks at the
23 bottom of this page to electronic systems,
24 and what the Office of Diversion Control says
25 in 1998 is: Using a computer to manage and

1 report on high-volume transaction business
2 activities with extremely short order cycle
3 times receipt to delivery, is the only viable
4 cost-effective methodology for the reporting
5 of orders which may be considered excessive
6 or suspicious.

7 That's what they said, correct?

8 A. That's what this statement
9 says. That's what the committee placed in --
10 that's what the statement says.

11 Q. And nowhere in this 1998
12 suspicious order reporting system that you
13 see on page 2247 is there anything about
14 stopping shipments of Schedule II through V
15 controlled substances. That's not on this
16 page, is it?

17 A. Which page are you referring
18 to?

19 Q. Page 2247, Exhibit 2,
20 Suspicious Order Reporting System of 1998.

21 A. There's nothing on that
22 particular page.

23 Q. Should distributors rely on
24 information they receive from DEA?

25 A. So my general answer to that

1 question would be yes, but I guess I'd have
2 to say it would depend on the topic and the
3 type of question and the information they
4 receive.

5 Q. Is being told -- strike that.

6 If a distributor is told you're
7 doing the right things and heading in the
8 right direction with respect to a suspicious
9 order monitoring program, is that an implicit
10 approval from DEA of the suspicious order
11 monitoring program that that distributor is
12 using?

13 A. Well, I think it could be taken
14 as an implicit approval, but then to know the
15 whole totality of what occurred to just have
16 that one statement, it could be a simple
17 aspect of the system.

18 So from -- and so I'll agree
19 but I -- but it depends on what the topic is
20 and what the question is and the complexity
21 of it.

22 Q. So if someone at DEA reviewed a
23 suspicious order monitoring system and told a
24 distributor you're doing the right things and
25 heading in the right direction, that's

1 implicit approval of the system they just
2 reviewed, correct?

3 A. It is, but again, in my
4 experience and in doing cases, I've had other
5 cases where a diversion investigator would
6 make a similar type comment to a registrant
7 and the system was not satisfactory.

8 So --

9 Q. Does that mean the diversion
10 investigator doesn't know what they're doing?

11 A. That could be one possible
12 explanation. I can't --

13 Q. How many diversion
14 investigators do you believe work at DEA and
15 don't know what they're doing?

16 MR. FULLER: Object to form.

17 A. I have no idea, sir.

18 BY MR. PYSER:

19 Q. While you were there, did you
20 believe your colleagues were competent?

21 A. Would the universe be all
22 diversion investigators? I would have to say
23 no, because I know of a couple that would
24 make statements that were not within the
25 guidance or the guidelines of what DEA would

1 expect in regards to approving and commenting
2 on suspicious order systems.

3 Generally speaking, yes.

4 Q. How about Kyle Wright?

5 MR. FULLER: Object to form,
6 outside the scope.

7 A. I've worked with Kyle Wright
8 and I've been present at one of his
9 presentations. I believe he's highly
10 competent. Sometimes I believe that he
11 doesn't articulate his subjects very well. I
12 believe his knowledge base is high, but I'm
13 not sure that I would say that his
14 articulation of some of that knowledge is
15 very well.

16 BY MR. PYSER:

17 Q. Did you ever file a complaint
18 while you were at DEA or complain to a
19 supervisor that you believed things that Kyle
20 Wright was saying in his presentations were
21 inappropriate?

22 MR. FULLER: Object to form.

23 Don't answer that question based on
24 your Touhy authorization. Way outside
25 the scope, Counsel.

1 MR. PYSER: Are you going to
2 refuse to answer that question?

3 THE WITNESS: Yes, sir, on the
4 advice of my counsel.

5 BY MR. PYSER:

6 Q. You're relying here today on
7 your experience at DEA, correct? That's why
8 you consider yourself an expert?

9 A. That's -- yes, sir, that's one
10 of my strengths, that my experience and then
11 the results of my experience, the Masters
12 case, the subsequent ruling, the Mallinckrodt
13 case.

14 Q. In your report around page 48,
15 you describe Cardinal Health's suspicious
16 order monitoring system as having two
17 operational aspects. So the first aspect you
18 talk about is ingredient limit reports?

19 A. Yes, sir.

20 Q. And the second one are reports
21 of excessive orders, correct?

22 A. Yes, sir.

23 Q. The ingredient limit reports,
24 those are submitted on a monthly basis from
25 each Cardinal distribution center to the

1 local DEA office, correct? That was the
2 practice at the time?

3 A. Yes. Post distribution of the
4 drugs, at the conclusion of a month, they
5 would submit the report, yes, sir.

6 Q. And DEA would receive that
7 report on a monthly basis post distribution
8 of the drugs, correct?

9 A. I guess I would make that
10 assumption. I never saw them. I wasn't
11 there at some of the time period. I've never
12 received them personally, but I don't have
13 any information to not believe that
14 statement.

15 Q. Where you were was in Detroit
16 and Cardinal Health didn't have a
17 distribution center in your region, correct?

18 A. That's correct.

19 Q. Now, you list some of the
20 ingredient limit reports in your report,
21 correct?

22 A. Yes, sir.

23 MR. PYSER: Let me mark this
24 one for you.

25 (Whereupon, Deposition Exhibit

1 Rafalski-11, Ingredient Limit Report,
2 CAH_MDL_PRIOROD_DEA07_01465435 -
3 CAH_MDL_PRIOROD_DEA07_01465712, was marked
4 for identification.)
5 BY MR. PYSER:

6 Q. I'm marking Exhibit 11. This
7 is the first ingredient limit report that you
8 mentioned in your report for this case. This
9 is a document -- it's a couple hundred pages
10 long?

11 A. It is.

12 Q. And this is one month's report
13 from one distribution center, correct?

14 A. Yes, sir.

15 Q. So you can multiply this out in
16 terms of the information that Cardinal Health
17 is providing to DEA on a monthly basis for
18 each of its 20-some-odd distribution centers,
19 correct?

20 A. Yes, sir.

21 Q. Now, I want to draw your
22 attention to Bates number 1465496. Are you
23 there with me?

24 A. I am.

25 Q. Okay. Now, on that page

1 there's a run date, so the date of this
2 report, of September 4th, 2005, right?

3 A. Yes.

4 Q. Okay. And it labels itself an
5 ingredient limit report, and looking again at
6 that Bates page I gave you ending 496?

7 MR. FULLER: I'm sorry, say the
8 Bates number again.

9 MR. PYSER: Ending in 496.

10 MR. FULLER: Oh, I got it,
11 sorry.

12 BY MR. PYSER:

13 Q. It has factor used of 4.0.
14 Do you see that?

15 A. Yes, sir.

16 Q. Okay. And underneath that,
17 there's a customer name, the Fredrick County
18 Health Department. And the ingredient? It's
19 about halfway down the page.

20 A. Yes.

21 Q. And the ingredient is
22 buprenorphine hydrochloride?

23 A. Yes, sir.

24 Q. And it lists the customer total
25 versus the ingredient limit?

1 A. Yes, sir.

2 Q. So the factor that's used, this
3 factor of 4, that's right there on the face
4 of this ingredient limit report sent to DEA,
5 correct?

6 A. It is.

7 Q. And to your knowledge, DEA
8 never told Cardinal Health you should use a
9 different factor, use some other factor other
10 than 4?

11 A. In my research for completing
12 my report and then also based on my
13 experience working there, I'm not aware that
14 anyone ever told them not to use the factor
15 of 4.

16 Q. Another critique -- you can put
17 the ingredient limit report aside. It's a
18 big document. Get in your way otherwise.

19 On page 58 of your report, you
20 level a criticism at Cardinal because there's
21 an increase in the amount of oxycodone from
22 the Wheeling, West Virginia distribution
23 center, correct?

24 A. Yes, sir.

25 Q. The DEA field office that

1 received the ingredient limit reports like
2 Exhibit 11 from the Wheeling distribution
3 center, they would have seen those increases
4 as well because it's right there in the
5 document, right?

6 A. I don't know what the DEA
7 office that received them would have seen or
8 not seen. I don't know if they would have
9 looked back historically.

10 I offered this opinion in my
11 report because I believe it's something that
12 Cardinal should have seen.

13 Q. Okay. So you don't have any
14 reason to think DEA was incapable of looking
15 at the ingredient limit reports like
16 Exhibit 11 and looking at a trend, correct?

17 A. I don't have any information
18 whether they were or weren't, sir.

19 Q. Okay. And DEA also receives
20 ARCOS information from every transaction that
21 every distributor makes of a controlled
22 substance, Schedule II controlled substance,
23 including Cardinal, correct?

24 A. They do, but in a different
25 way. So this -- just so clarification, I

1 think our discussion was that this would be
2 received at the -- at the office that would
3 be nearest the distribution center. The
4 ARCOS gets received at headquarters and it's
5 a totally different --

6 Q. Understood. So --

7 A. Okay. Just clarifying that.

8 Q. So DEA has at the local field
9 office, they've got the information about
10 distributions from the ingredient limit
11 reports that are reported by Cardinal because
12 they went over the factor 4.

13 And then also, at the national
14 office, DEA has the ARCOS report which has
15 every transaction from a distributor to a
16 pharmacy, correct?

17 A. It has every Schedule II
18 transaction, Schedule III narcotics and one
19 other -- one other category of drugs. It's
20 not all transactions.

21 Q. So any increases could have
22 been seen in the ARCOS data as well?

23 MR. FULLER: Form.

24 MR. PYSER: Let me rephrase the
25 question.

1 BY MR. PYSER:

2 Q. So any increases in the amount
3 of oxycodone being shipped from the Cardinal
4 distribution center in Wheeling to Cardinal's
5 customers could have been seen in the ARCOS
6 data reported to DEA?

7 MR. FULLER: Form.

8 A. So --

9 MR. FULLER: Go ahead.

10 A. Just a clarification. The
11 ARCOS data gets submitted on a monthly or
12 quarterly basis to the DEA, and it's -- I
13 think they used the term "cleansed," but it's
14 corrected for any potential errors, and then
15 it's deposited into a huge database and it's
16 designed to be queried.

17 So what you said is potentially
18 true if somebody would -- would query that
19 particular topic, but I just want to make
20 sure that we -- I understand it's not
21 automatically reviewed or there's not a
22 process to do what you said it did.

23 **REDACTED**

24

25

1 **REDACTED**

2 BY MR. PYSER:

3 Q. During this time when you're
4 criticizing Cardinal for an increase in
5 oxycodone shipments, DEA had also increased
6 the quota of oxycodone available in the
7 United States for legitimate medical
8 purposes, correct?

9 MR. FULLER: Object to form.

10 If you know.

11 A. I don't know.

12 BY MR. PYSER:

13 Q. You don't know when or if DEA
14 increased the quota for oxycodone in the
15 country?

16 MR. FULLER: Same objection.

17 A. I didn't review that
18 information, so I don't know.

19 BY MR. PYSER:

20 Q. Do you think that's something
21 as a diversion investigator you should know?

22 MR. FULLER: Object to form.

23 A. No, sir.

24 BY MR. PYSER:

25 Q. The DEA license held by the

1 Wheeling distribution center of Cardinal
2 Health, that license has never been suspended
3 or revoked by DEA, correct?

4 A. That's a correct statement.

5 Q. Okay. So we've talked about
6 the ingredient limit reports. I want to go
7 back to the second aspect of Cardinal
8 Health's pre-2007 system you talked about in
9 your report, and that's the reports of
10 excessive purchase orders on a daily basis to
11 DEA before shipment.

12 A. Uh-huh.

13 Q. And that's around page 59 of
14 your report.

15 A. The pickers and packers? Yes,
16 sir.

17 Q. So Cardinal Health's policies
18 instructed personnel to monitor and identify
19 individual orders that appeared excessive
20 before they were shipped, correct?

21 A. Yes, sir.

22 Q. Now, you, in your report on
23 page 59, you list a couple dosage limits for
24 select medications, correct?

25 A. Yes, sir.

1 Q. Now, there are some customers,
2 isn't it true, who are going to consistently
3 order over these limits because they're large
4 customers; isn't that right?

5 MR. FULLER: Object to form,
6 vague.

7 A. Well, I guess that is a
8 possibility. I didn't see anything that
9 would not require an employee of Cardinal to
10 follow this procedure that would exempt any
11 type of customers or have them fail to take
12 this appropriate -- or this -- not
13 appropriate -- take this action as required.
14 BY MR. PYSER:

15 Q. What the policy says is on a
16 daily basis, cage-involved personnel should
17 be policing and identifying individual orders
18 that appear excessive in relation to what
19 other customers are buying and/or the
20 customer's purchase history. In these
21 situations DEA should be notified if possible
22 before the order is shipped and a copy of all
23 such orders should be maintained in the
24 division's suspicious order file, along with
25 the regulatory agency contact form noting any

1 specific instructions from DEA.

2 Correct?

3 A. Yes, sir.

4 MR. FULLER: And I don't know
5 what he's reading from, but if you
6 want to pull the policy to make sure
7 he's reading it accurately, you're
8 welcome to do so. I don't know --

9 MR. PYSER: Counsel, we can
10 drop the speaking objection. He's
11 already answered.

12 MR. FULLER: No, I won't drop
13 the speaking objections.

14 BY MR. PYSER:

15 Q. So let's take an example, the
16 Cleveland Clinic. They're in Cleveland,
17 Ohio. It's a large medical facility.

18 Would you expect the
19 Cleveland Clinic to order, when they order
20 from Cardinal Health, more than 800 capsules
21 of hydrocodone at a time?

22 A. I don't really have an opinion
23 either way. It's a possible reasonable
24 assumption, but without seeing the
25 distribution datas or the purchasing

1 requests, I don't know.

2 Q. And you haven't looked at that
3 information. You haven't gotten to that
4 level of granularity in your work?

5 MR. FULLER: Form.

6 A. I didn't review the Cleveland
7 Clinic or the ingredient limit reports for
8 specifically looking for the Cleveland
9 Clinic. I focused on the retail or the
10 pharmacies.

11 BY MR. PYSER:

12 Q. Do you believe that Cardinal
13 Health should have stopped shipping
14 hydrocodone and other pain medicine to the
15 Cleveland Clinic based on the fact that there
16 were times when the Cleveland Clinic ordered
17 more than 800 tabs of hydrocodone at a time?

18 A. So how I'll answer that is that
19 this policy was set up by Cardinal and it's
20 in response to how Cardinal identified the
21 scope of the businesses they supply.

22 So my opinion is based on the
23 policy that Cardinal set up. I didn't set up
24 this policy for them; they did. So if their
25 policy requires them to take an act and

1 they've set the limit up at 800 tablets, then
2 unless they modify their policy or they have
3 some exception, I -- this is their policy,
4 and this is what they're requiring their
5 employees to do.

6 Q. Sir, do you think that it would
7 be appropriate to deny cancer patients at the
8 Cleveland Clinic medication based on this
9 absolute limit? Yes or no?

10 MR. FULLER: Object to form.

11 That wasn't the same question.

12 A. Well, I think to answer that
13 question, if that did occur because they had
14 a defective suspicious order system, they
15 should correct that so that doesn't occur.

16 But so -- I guess that's a
17 hypothetical that I don't really want to
18 comment on, but the main thing that I want to
19 make sure is that -- on my statement is that
20 this is Cardinal's policy, and this is what
21 they're requiring their employees to do.

22 BY MR. PYSER:

23 Q. Sir, where do you get the
24 opinion that there was no flexibility around
25 this policy and Cardinal Health had no choice

1 in its policy but to stop shipment of any
2 order above these limits?

3 A. I didn't see any documents or
4 any policies that gave the employees that
5 flexibility.

6 Q. You make reference in your --
7 in your report to the deposition of Steve
8 Reardon.

9 Do you recall that?

10 A. Yes, sir.

11 Q. Did you read Mr. Reardon's
12 entire deposition?

13 A. I believe I did, yes, sir.

14 Q. Every page?

15 A. Well, yes, sir, I believe so.

16 Q. No one from the plaintiffs'
17 counsel pointed you to certain pages and told
18 you to read those but not others?

19 A. No, sir.

20 Q. Did DEA require a particular
21 form or format to report suspicious orders?

22 A. No. The -- how a suspicious
23 order is reported to the DEA is up to the
24 individual registrant.

25 Q. So suspicious orders can be

1 reported in an ingredient limit report like
2 that, correct?

3 A. The way they're reported and
4 how they're delivered, that's up to the
5 registrant.

6 Q. Okay. And if a registrant
7 wanted, they could report a suspicious order
8 to DEA via a phone call, correct?

9 A. They could. If I was to
10 provide them guidance, I wouldn't recommend
11 that because it's difficult to record and
12 document notification, but there would be
13 nothing in the regulations that would
14 prohibit them from doing that.

15 Q. If DEA didn't want to receive
16 phone calls, they of course could tell
17 registrants don't call us, correct? They
18 have that ability.

19 A. Well, if you're asking that
20 based on my last response, that's not what
21 I'm indicating. I'm not saying that I would
22 advocate to tell them don't call me again.

23 What I'm saying is if they were
24 to call to report a suspicious order, I would
25 take the information and document it and act

1 on it, but I would also give some guidance
2 that they may want to deliver the suspicious
3 order report in a way that they have
4 verification.

5 Q. Did you ever give that guidance
6 to Cardinal Health?

7 A. No, sir.

8 Q. At page -- strike that.

9 For Cardinal Health, are you
10 aware that excessive order reports that are
11 described in your report were often
12 memorialized in agency contact forms?

13 MR. FULLER: Object to form.

14 A. I'm aware -- I'm aware that
15 it's a requirement of the policy, also is --
16 I believe that I've only viewed two completed
17 forms, those agency contact forms, in regards
18 to suspicious -- or suspicious order reports
19 or as far as this activity.

20 Now, I think that form, if I
21 understand it correctly, is a multiuse form,
22 so it could be used by any contact at
23 different agencies, and the two that I'm
24 speaking of are just in regards to notifying
25 the DEA in regards to orders.

1 BY MR. PYSER:

2 Q. You state at page 60 of your
3 report, quote, I've not been able to locate
4 any reports related to orders in excess of
5 the daily limit for the Wheeling distribution
6 center produced in this matter.

7 Do you recall that?

8 A. That's a correct statement.
9 The two that I reviewed I think were a
10 different distribution center.

11 Q. Okay. How much time did you
12 personally spend looking for agency contact
13 forms from the Wheeling distribution center?

14 A. I spent considerable time, and
15 then also I think it was part of the
16 requirement that in the -- in the response to
17 discovery to make -- advise on that matter
18 too, so I think if they existed, there would
19 have been other documents that would have
20 indicated they did exist.

21 Q. Now, if we're talking about the
22 pre-2007 system, we're now here in 2019, so
23 those forms would be 12 or 13 years old at a
24 minimum, correct?

25 A. Yes, sir.

1 Just for clarification, you're
2 talking the agency contact forms or the
3 ingredient limit reports?

4 Q. Agency contact forms.

5 A. Okay.

6 Q. From the pre-2007 time period.

7 (Whereupon, Deposition Exhibit
8 Rafalski-12, Regulatory Agency Contact
9 Sheet, CAH_MDL_PRIOROD_DEA07_00868973,
10 was marked for identification.)

11 BY MR. PYSER:

12 Q. So I'm marking as Exhibit 12 an
13 agency contact form dated February 6th, 2007.
14 Was this one of the forms that you reviewed
15 in your preparation for your report?

16 A. I -- I don't recall seeing this
17 form before.

18 Q. Okay. So this is a 2007 agency
19 contact form. The purpose of the contact is
20 reporting excessive purchases of oxycodone.

21 Do you see that --

22 A. I do.

23 Q. -- in the Purpose of Contact
24 section?

25 And the name, address and

1 telephone number of the DEA representative is
2 Jeff Conners.

3 Do you see that?

4 A. Yes, sir.

5 Q. Do you know Mr. Conners?

6 A. I know the name. I've probably
7 met him once or twice before. But to say
8 know him, I'm not familiar with him
9 personally.

10 Q. But you know that he worked for
11 DEA?

12 A. Yes, I -- I think I indicated
13 that, yes, sir.

14 Q. And the advice that he gave
15 Cardinal Health or the response that he gave
16 Cardinal Health was, quote: Advise to keep
17 sending monthly ILR report.

18 Do you see that?

19 A. I see that statement, and I
20 acknowledge that's what the employee wrote
21 down for Cardinal Health. I don't know that
22 that's what Mr. Conner said. And I say that
23 because I've -- in my experience, I have
24 reviewed other documents, even things that I
25 was involved in where people wrote things

1 that I didn't say.

2 Q. Sir, you've not spoken to
3 either Mr. Connors or Ms. Oglesby, who filled
4 out this form, about the form?

5 A. I have not.

6 Q. Okay. Yet, you're questioning
7 the veracity of the statement in here?

8 A. I'm just saying that -- it's
9 not the veracity. I'm just -- and I'm going
10 to acknowledge that is what was said, but I
11 just don't know if that's what Mr. Connors
12 said to Ms. Oglesby.

13 Q. You don't have any specific
14 reason to doubt that that's what's said?

15 A. No, sir, just based on my
16 experience that there's been other times when
17 statements were made that weren't -- that
18 didn't -- weren't accurate.

19 Q. It's true that upon receiving a
20 contact of a suspicious order by phone, DEA
21 also sometimes told Cardinal Health to ship
22 the product that it was reporting, correct?

23 A. I'm not aware that that ever
24 occurred. Could I ask a question about this?

25 Do you happen to have the order

1 that was required to be attached to it?

2 Q. I do not have that with me, and
3 it's 13 years ago, so I can't make a
4 representation to you whether or not it still
5 exists.

6 A. Okay.

7 Q. Does DEA still have the order?

8 A. 2007? There -- oxycodone,
9 there would be an ARCOS data entry.

10 Q. Beyond the ARCOS entry, would
11 DEA have any other record of this
12 transaction?

13 A. No, sir.

14 Q. Okay. Would DEA have any other
15 record of this communication?

16 MR. FULLER: Object to form,
17 outside of scope. Counsel, this is
18 also indicated that it's from the
19 Findlay distribution center, which I
20 don't even believe we've been provided
21 transactional data from the Findlay
22 distribution center.

23 MR. PYSER: The witness has
24 already testified he looked at reports
25 from outside of --

1 MR. FULLER: No, no, I
2 understand that. That brings us back
3 to the issue that we talked about at
4 the very beginning, that most of the
5 distribution into CT1 was from the
6 Wheeling distribution center. This
7 shows that there wasn't, and there
8 were suspicious orders shipped by
9 Findlay.

10 And I believe Cardinal now
11 needs to supplement with the Findlay
12 distribution data for CT1, for all
13 Findlay distribution data.

14 MR. PYSER: Mr. Fuller, first
15 of all, it's a speaking objection.

16 MR. FULLER: I'm going to
17 move -- I'm going to move for that.

18 MR. PYSER: Let me explain to
19 you that this is not an order placed
20 by a pharmacy in CT1. If you'd read
21 the document, you would see the city
22 is Columbus, Ohio, which is not part
23 of CT1.

24 MR. FULLER: I see that.

25 MR. PYSER: So you can take

1 your objection and you can put it at a
2 more appropriate time.

3 BY MR. PYSER:

4 Q. Sir, do you know a DEA
5 investigator named Chuck Carpenter?

6 A. No, sir.

7 Q. On page 61 of your report, you
8 claim that Cardinal Health was delivering
9 oxycodone illegally to a pharmacy known as
10 Ross Westbank Pharmacy.

11 Do you recall that?

12 A. What page are you on?

13 Q. 61.

14 A. Yes, sir.

15 Q. Where's Ross Westbank Pharmacy
16 located?

17 A. I don't know. Let me...

18 Q. Well, it makes up an entire
19 schedule to your report, Schedule III.

20 A. I was going to ask to pull
21 those records.

22 Q. And I'll represent to you that
23 hundreds of times in your very own report, it
24 says Ross Westbank Pharmacy is located in
25 Hudson, Wisconsin.

1 A. Okay.

2 Q. Sir, do you have any evidence
3 to support a connection between the
4 pharmaceuticals shipped to Ross Westbank in
5 Hudson, Wisconsin and use of those
6 pharmaceuticals in Cuyahoga or Summit County?

7 A. I don't think that appears in
8 my report to attribute the specific
9 distributions. I think it goes into my
10 report to the conduct of Cardinal Health,
11 where the regulations and the compliance
12 department was operated centrally out of the
13 headquarters.

14 Q. So that's a no to my question?

15 A. Well, I guess you asked me how
16 I used it. And --

17 Q. No, I --

18 A. Could you restate the question?
19 I'm sorry.

20 Q. Do you have any evidence to
21 support a connection between the
22 pharmaceuticals shipped to Ross Westbank in
23 Hudson, Wisconsin and the use of
24 pharmaceuticals in Cuyahoga or Summit County?

25 A. No, sir. Just the conduct by

1 the Cardinal company.

2 MR. PYSER: Move to strike
3 everything after "No, sir."

4 BY MR. PYSER:

5 Q. Do you know whether Ross
6 Westbank Pharmacy appeared on Cardinal's
7 ingredient limit reports to DEA?

8 A. I do not know, sir.

9 Q. Are you aware that DEA has
10 taken the position that there are some
11 legitimate medical sales that occur over the
12 Internet?

13 A. What would the time frame for
14 that statement be?

15 Q. Well, you tell me. What's
16 DEA's position about --

17 A. Well, there is -- there was
18 approval eventually of Internet pharmacies.

19 Q. When did that happen? Roughly?
20 You don't have to give me an exact date.

21 A. I really don't want to guess,
22 and I don't have my Code of Federal
23 Regulations here. It was post the Ryan
24 Haight Act or in conjunction with the Ryan
25 Haight Act. I don't want to guess at a year.

1 Q. At any time that you're aware
2 of, was there a federal regulation or rule
3 that prevented individuals from ordering
4 noncontrolled substances through the mail,
5 say, blood pressure medication? Is that okay
6 to receive that through the mail?

7 A. I never received any guidance
8 or training on acquisition of noncontrolled
9 substances pursuant to a prescription, so I
10 don't know the answer to that. I never
11 reviewed it as part of this opinion either.

12 Q. On pages -- I want to go back a
13 little bit in your report, pages 49 through
14 50. You list a series of enforcement actions
15 against Cardinal Health.

16 Do you see that?

17 A. Yes, sir.

18 Q. None of the enforcement actions
19 against Cardinal Health that you list in your
20 report occurred in Cuyahoga or Summit County,
21 correct?

22 A. The purpose for listing these
23 was to demonstrate the failure to maintain
24 effective controls against diversion. I do
25 acknowledge that none of them specifically

1 are against the distributions to Cuyahoga
2 County.

3 Q. Okay. And none of them involve
4 the Wheeling, West Virginia distribution
5 center, correct?

6 A. That's correct.

7 Q. On page 52 of your report, you
8 have a paragraph. The first full paragraph
9 talks about a 2005 New York Attorney General
10 investigation?

11 A. Yes.

12 Q. And you write: The matter
13 involves, amongst other allegations, price
14 diversion with closed-door pharmacies that
15 engaged in contract pricing.

16 Do you see that?

17 A. Yes, sir.

18 Q. So this New York Attorney
19 General investigation you're speaking about,
20 it involved pharmacies that were buying
21 medication and reselling it to other
22 pharmacies; is that a correct understanding?

23 A. Yes, sir.

24 Q. Okay. And that wasn't limited
25 in any way to controlled substances; it was

1 the buying and selling of medication more
2 generally than that. That's price diversion,
3 correct?

4 MR. FULLER: Form.

5 A. So again, this goes to the
6 conduct of the Cardinal facility, but the
7 answer to your question would be yes.

8 BY MR. PYSER:

9 Q. In what you've reviewed related
10 to the New York Attorney General
11 investigation from 2005, you've not formed
12 any opinion that opioids were being diverted
13 to any patient without a legitimate
14 prescription, correct?

15 A. In my review of that, I don't
16 recall that there was any specific reference
17 to opioids.

18 Q. Sir, do you have your tax
19 returns from 13 years ago, in 2006?

20 A. Unfortunately, I would probably
21 answer yes. I believe my wife has my utility
22 records from back at that time. Although I
23 would -- before you ask me again, I would
24 acknowledge that's not the norm.

25 Q. So most people don't keep their

1 tax returns going back 13 years, right, in
2 your experience?

3 A. Well, I haven't conducted any
4 surveys or asked any people, but generally
5 speaking, people don't keep those kind of
6 records for that length of time.

7 Q. They may have paid their taxes
8 even though they no longer have the tax
9 returns from 13 years ago, correct?

10 A. Well, I think in some of those
11 records, I guess retention -- and I'm not
12 sure why there would be a retention because I
13 think there's some law or regulation on how
14 far the IRS could go back and look at your
15 previous tax returns. Seem to think seven
16 years comes to mind.

17 So there would be no reason to
18 retain them past that period of time as far
19 as I could see, unless that's just what you
20 wanted to do.

21 Q. So it's your layman's
22 understanding that the IRS tells taxpayers
23 the length of time they need to retain their
24 tax returns in case there's any further
25 inquiry, right?

1 MR. FULLER: Object to form.

2 A. I don't think they tell them
3 that. I think that -- and I don't think the
4 IRS really tells you that either, maybe the
5 law does. I believe in conversations with an
6 accountant, I think they tell you how far
7 back you're required to keep records for a
8 possible audit.

9 BY MR. PYSER:

10 Q. In your report, you come to the
11 opinion that if a distributor's unable to
12 locate a due diligence file, say, from 2006,
13 that no due diligence was done, correct?

14 If you can't put your hands on
15 it today, you make the assumption that
16 nothing was done; is that right?

17 A. Yes, sir.

18 Q. Is it possible that due
19 diligence was done back in 2006 or even
20 earlier, but those records weren't retained?

21 A. Well, my opinion on that matter
22 is if there were no records retained, then
23 there was no due diligence because there's no
24 record of it.

25 And not just from the

1 standpoint of the physical piece of paper,
2 but moving forward even though it's 13 years
3 later, I think there has to be a
4 comprehensive history in a due diligence to
5 make some decisions relative to that
6 pharmacy.

7 Now, albeit 13 years back is a
8 lot different than the industry is today, but
9 I don't think it would be prudent for any
10 distributor to throw away any record in
11 regards to a pharmacy.

12 Q. Even a pharmacy that's no
13 longer a customer?

14 A. Well, I think in regards to
15 that topic, the -- depending on the scenario,
16 if it was a terminated or this customer no
17 longer wanted to do any business with
18 Cardinal, that doesn't mean they could always
19 come back and reapply to be a customer again.

20 And I think that's one of the
21 critical examples of why you need to retain
22 that, because you would be starting all over
23 again, and you're negating the history,
24 either positive or negative, of the work you
25 did in regards to that registrant.

1 Q. When a pharmacy closes its
2 doors, let's say a pharmacy goes out of
3 business, at that point is a distributor free
4 to get rid of the records about that pharmacy
5 or do they have to keep it even after that
6 point in your view?

7 A. Well, there's no regulatory
8 guidance, the maintenance of effective
9 controls. I guess if you went to the extreme
10 and the owner pharmacist died, but if he --
11 if he just closed his doors and he moved on
12 and he might potentially open another
13 company, I would say, if it was my decision
14 as a registrant, I would keep the record.

15 Q. When you were performing cyclic
16 investigations -- is it an investigation or
17 an audit? What's the right term?

18 A. Well, some people call them
19 cyclic. Some people call them work plans.
20 Some call them regulatories. It goes by all
21 those different names.

22 Q. So when you were visiting a
23 distributor in your job working as a
24 diversion investigator, did you tell the
25 distributors you visited that it was your

1 expectation that all records related to
2 pharmacy due diligence would be kept
3 indefinitely?

4 A. I believe I would consistently
5 discuss that. Saying that those aren't
6 required records, so that would be a
7 discussion under security, but yes. And I
8 was present -- so there would be my training
9 in regards to the distributor briefings. I
10 was present at a distributor briefing to
11 actually -- because I wanted to learn how
12 they occurred, and Mr. Kyle Wright, we had
13 spoke about him earlier, he would make it
14 clear that -- in pretty common terms that if
15 you don't document it, it doesn't exist.

16 Q. So while you would inform
17 distributors in your recollection that you
18 believed they should do it, you also told
19 them that it was not a required record to
20 maintain due diligence, correct?

21 A. I don't know if I would inform
22 them of that --

23 MR. FULLER: Object to form,
24 misstates his testimony.

25 A. I don't know if I would

1 specifically say it's something they did or
2 didn't do. I would just give them in some
3 matters guidance. It would be a guidance
4 that -- because in most regulatory
5 investigations, I may ask to see some due
6 diligence on a specific customer, and
7 sometimes it would come up when I asked for
8 it that they -- the registrant would tell me
9 that it's not a required record.

10 So the option was this is -- as
11 part of a work plan or a regulatory
12 investigation, a registrant wouldn't have to
13 show me the due diligence. In that case, I'd
14 have to subpoena.

15 BY MR. PYSER:

16 Q. You're one diversion
17 investigator when you were working at DEA,
18 correct?

19 A. Yes.

20 Q. Do you know one way or the
21 other whether the diversion investigators who
22 visited Cardinal Health's facilities ever
23 told them about this indefinite record
24 retention policy that you're putting forward
25 in your expert report?

1 MR. FULLER: Objection. And
2 remind you of your Touhy obligation.
3 Anything that is internal policy at
4 DEA or communicated while you were on
5 the job is outside the scope of what
6 you're authorized to testify to.

7 A. I'm not aware.

8 BY MR. PYSER:

9 Q. So on page 50 of your report,
10 you have a chart that talks about suspicious
11 orders reported in the CT1 jurisdictions,
12 right?

13 A. Yes.

14 Q. Okay. And there's two columns,
15 pre-shipment reporting and then -- on the
16 left, and on the right, post-shipment
17 reporting, right?

18 A. Right. Yes, sir.

19 Q. Okay. On the right side, the
20 post-shipment reporting, it's blank until
21 2005, correct?

22 A. Yes, sir.

23 Q. And that's blank there because
24 you know from testimony that Cardinal Health
25 was submitting ingredient limit reports to

1 DEA, but we just no longer have those
2 records; is that right?

3 A. Sir, I believe my report says
4 that I could not find those -- I could not
5 find -- those weren't provided to me and I
6 did not find those reports.

7 Q. You also reviewed the testimony
8 of Steve Reardon we talked about earlier
9 today, and he said Cardinal Health was
10 sending ingredient limit reports to the DEA
11 beginning in the early '90s, correct?

12 A. I don't have a recollection of
13 that exact statement in his deposition.

14 Q. Did you have any reason to
15 believe Mr. Reardon wasn't telling the truth
16 if that is, in fact, what he said?

17 A. No, I don't have any
18 independent knowledge of not -- whether to
19 believe him or not to believe him.

20 Q. So on page 50 we have blanks
21 under post-shipment report, where it's
22 unknown, but you filled in zeros on the left
23 side for pre-shipment reports all the way
24 from 1996 to 2012, correct?

25 A. Yes.

1 Q. We talked earlier about these
2 agency contact forms for phone calls to DEA?

3 A. Yes, sir.

4 Q. Is it possible that at some
5 point from 1996 through 2012 employees from
6 Cardinal Health may have called DEA before
7 shipping an order that was destined for
8 Cuyahoga or Summit County?

9 A. If that occurred, I would have
10 an expectation to see one of the agency
11 contact forms.

12 Q. But knowing that we don't have
13 any agency contact forms from Wheeling, West
14 Virginia, is it possible that people spoke on
15 the phone, but today, from 1996, it's
16 23 years later, so 23 years later, is it
17 possible a phone call was made but we don't
18 have a record of it?

19 MR. FULLER: Objection,
20 misstates evidence.

21 A. So I can only comment on the
22 facts of which I know and what records exist.
23 I don't make comments on hypothetical
24 situations of whether it could have occurred
25 and there was no documentation or it's lost

1 or --

2 BY MR. PYSER:

3 Q. Well, sir, you do, because you
4 put a zero there instead of leaving it blank
5 like you did on the other side.

6 So isn't it more accurate that
7 where you don't know, you should leave it
8 blank like you did on the right-hand side,
9 rather than filling in zeros when you don't
10 have any evidence one way or the other?
11 Wouldn't that be a better way to write your
12 report?

13 A. I guess that's open to your
14 interpretation. I'm confident with putting
15 zeros because I found no documents.

16 Q. So when you don't know
17 something, you assume it wasn't done in your
18 report, correct?

19 A. Well, I -- if I don't see a
20 record that I believe should have been
21 retained, then it -- I guess -- I don't know
22 if that's an assumption. It doesn't exist.
23 I can't make an opinion of that a record
24 existed when I don't have any documentation
25 that it did exist.

1 MR. PYSER: We've been going
2 about an hour. Let's take a break.

3 THE WITNESS: Sure.

4 THE VIDEOGRAPHER: Going off
5 the record at 3:59 p.m.

6 (Recess taken, 3:59 p.m. to
7 4:10 p.m.

8 THE VIDEOGRAPHER: We're back
9 on record at 4:10 p.m.

10 BY MR. PYSER:

11 Q. Welcome back, Mr. Rafalski.

12 A. Thank you.

13 Q. Directing your attention to
14 page 52 of your report, in the last
15 paragraph, you make a statement that Cardinal
16 Health provided almost preferential treatment
17 to its chain pharmacy accounts as compared to
18 their retail independent customers.

19 Do you see that opinion?

20 A. Yes, sir.

21 Q. And just over on to the next
22 page, you base that on a declaration of
23 Michael Mon?.

24 Do you see that?

25 A. Yes, sir.

1 Q. And, in particular, if you go
2 to page 13 of this document.

3 (Whereupon, Deposition Exhibit
4 Rafalski-13, Declaration of Michael A.
5 Mon?, CAH_MDL_PRIOROD_DEA12_00014053 -
6 CAH_MDL_PRIOROD_DEA12_00014081, was
7 marked for identification.)

8 BY MR. PYSER:

9 Q. I'm showing you a document now
10 that's been marked as Exhibit 13.

11 MR. FULLER: Thank you.

12 BY MR. PYSER:

13 Q. And on page 13 there's a
14 paragraph, it's paragraph 29. Do you see
15 that?

16 MR. FULLER: What exhibit
17 number is this?

18 MR. PYSER: 13.

19 MR. FULLER: Okay.

20 You said page 13 as well?

21 MR. PYSER: Yes. Exhibit 13,
22 page 13.

23 BY MR. PYSER:

24 Q. Are you with me, Mr. Rafalski?

25 A. I am.

1 Q. Now, what the paragraph or the
2 page that you cite in your report for that
3 statement says is: In 2009 -- and this is
4 Michael Mon?, Cardinal Health employee in the
5 anti-diversion team, he writes: In 2009, DEA
6 diversion investigator Michael Arpaio raised
7 a question about Cardinal Health's due
8 diligence files on its chain pharmacy
9 customers.

10 Do you see that?

11 A. Yes, sir.

12 BY MR. PYSER:

13 Q. And a little bit later down, it
14 says: Arpaio told Cardinal Health personnel
15 that he needed to contact DEA's attorney to
16 determine if Cardinal Health's due diligence
17 on chain pharmacies presented any problem.
18 Thereafter, I -- that's Mr. Mon? -- contacted
19 Mr. Arpaio and his supervisor,
20 Ms. Boockholdt, to discuss the question.

21 Do you see that?

22 A. Yes, sir.

23 Q. Okay. And a little bit further
24 down, it says: **REDACTED**

1 **REDACTED**

2

3

4

5

6

7

8

9 A. Yes, sir.

10 Q. Do you know Ms. Boockholdt and
11 Mr. Arpaio?

12 A. I know who Mr. Arpaio is, and I
13 think I've met him. I know who
14 Ms. Boockholdt is. I probably had some
15 interaction and conversations with her, not
16 in regards to this document, but just in
17 terms of my employment.

18 Q. And at the very end it states,
19 beginning on the last line: **REDA**

CTED

CTED

CTED

CTED

24 A. Yes.

25 Q. -- with respect to chain

1 pharmacy customers. DEA's own inspectors
2 have described Cardinal Health's SOM program
3 as one of the best among wholesale drug
4 distributors nationwide.

5 Do you see that?

6 A. Yes, sir.

7 Q. So this is the paragraph you
8 cited in your report, correct?

9 A. Yes, sir.

10 Q. Now, Ms. Boockholdt and
11 Mr. Arpaio, who interacted with Mr. Mon? in
12 2009, that was ten years ago, right, 2009?

13 A. Yes, sir.

14 Q. Who's in a better position to
15 understand Cardinal Health's suspicious order
16 monitoring process? Two DEA investigators
17 who spoke to Cardinal Health at the time or
18 yourself ten years later?

19 MR. FULLER: Object to form,
20 inadequate hypothetical.

21 A. I don't know what information
22 that either one of these diversion
23 investigators had to cause Mr. Mon? to make
24 this affidavit or --

25 ///

1 BY MR. PYSER:

2 Q. You've never spoken to
3 Ms. Boockholdt or Mr. Arpaio about the
4 statements in this paragraph, have you?

5 A. No, sir.

6 Q. You've never seen any statement
7 from Ms. Boockholdt or Mr. Arpaio
8 contradicting the statements in this
9 paragraph, have you?

10 A. I have not.

11 Q. In your report, you identify
12 one retail independent customer in Ohio from
13 Cardinal Health and speak about it. **REDA**

CTED

15 A. Yes, sir.

16 Q. And your conclusion or your
17 opinion is that the due diligence file as it
18 exists in 2018 does not sufficiently document
19 certain increases in oxycodone distributions
20 between 2004 and 2008, correct?

21 A. I'd like to get to that
22 section, but I know my --

23 Q. Take a look at page 53.

24 A. -- my report does state that.
25 And I think it also states, if I remember

1 correctly, there was three changes of
2 ownership -- actually, let me retract that.

3 There were three changes of DEA
4 numbers over a period of years, and that was
5 alarming to me, and I would have had an
6 expectation to see some explanation of why
7 that -- those DEA registration numbers
8 changed.

9 Q. Do you know who owned **R**
10 **E**

11 A. I'm not sure I knew or not. I
12 don't think it -- I don't -- I don't know.

13 Q. Do you know where the pharmacy
14 is located, was located?

15 A. Yes.

16 Q. Where?

17 A. It was located in a hospital.

18 Q. **REDACTED**

19 **REDACTED**
20 A. Yes, sir.

21 Q. Did you ever visit it?

22 A. No, sir.

23 Q. Do you know whether Cardinal

24 Health employees visited **REDACTED**

25 A. If they did visit, I don't

1 recall seeing any documentation of the visit
2 or results of the visit.

3 Q. Did you see documentation that
4 Mr. Mon?, the head of Cardinal Health's
5 anti-diversion program, personally visited
6 that pharmacy?

7 A. I don't have a recollection of
8 that.

9 Q. Is that something you should
10 have considered?

11 A. If he visited?

12 MR. FULLER: Form.

13 BY MR. PYSER:

14 Q. Yes.

15 A. I guess I'd have to see what
16 the results of that visit was. If he -- the
17 purpose of his visit and whether he conducted
18 due diligence and what his notations. I
19 don't recall reviewing any kind of file about
20 documenting the purpose or what occurred
21 during his visit.

22 Q. If there's a due diligence file
23 that does document Mr. Mon?'s visit, is that
24 something you should have reviewed as part of
25 your opinion?

1 A. Yes, sir, I think I would need
2 to consider that. I don't think it would
3 have changed some of the conduct that
4 occurred with -- in regards to the dosage
5 units and the increases, unless there's
6 something specific in there that I'm not
7 aware of.

8 Q. Do you know whether **REDACT**
9 **REDA** ever lost its DEA registration?

10 A. I'm not aware that it lost its
11 DEA registration, no, sir.

12 Q. Did DEA ever take any adverse
13 action against **REDACTED**?

14 A. Not that I'm aware of, no, sir.
15 But that doesn't minimize or alleviate the
16 conduct that I described in my report,
17 whether or not the DEA took action against
18 them.

19 MR. PYSER: Move to strike
20 everything after "Not that I'm aware
21 of, no, sir."

22 MR. FULLER: Object to the
23 motion.

24 BY MR. PYSER:

25 Q. Did you review a due diligence

1 file that made clear [REDACTED] **REDACT**
2 [REDACTED] from medical staff who are ASAM and
3 pain management certified?

4 A. I'd like to pull that document,
5 the due diligence file.

6 Q. Well, if you want to pull a
7 document, we're going to have to go off the
8 record.

9 MR. FULLER: No, he can do it.
10 You're asking the questions.

11 MR. PYSER: I asked him a
12 simple question.

13 MR. FULLER: If you want to
14 give him a due diligence file that's
15 cited in his report, then so be it.
16 He can pull it. You're the one that's
17 not showing him the documents.

18 Oh, so you had it.
19 Interesting.

20 MR. PYSER: Enough commentary,
21 Counsel.

22 MR. FULLER: Nah.

23 (Whereupon, Deposition Exhibit
24 Rafalski-14, 1/10/08 Brantley Memo
25 w/Attachment(s),

1 CAH_MDL2804_00000606 -

2 CAH_MDL2804_00000618, was marked for
3 identification.)

4 BY MR. PYSER:

5 Q. I'm showing you a document
6 marked as Exhibit 14. This is the file that
7 you reference in your report.

8 MR. FULLER: Thank you.

9 BY MR. PYSER:

10 Q. On the first page it states
11 that **REDACTED**

REDACTED

13 A. Yes, sir.

14 Q. On the second page, third
15 paragraph, it states: The account was
16 confirmed as being owned by a hospital,
17 again, and services oncology and hospice
18 patients.

19 Mr. Rafalski, in your
20 experience, do oncology and hospice patients
21 use more pain medication than the average
22 population?

23 A. Well, I'm not a physician, but
24 I would have to say in my experience that
25 that would be a logical assumption.

1 Q. It goes on to say: In
2 addition, they -- [REDACTED]
3 [REDACTED] -- are inspected by the Board of
4 Pharmacy on a monthly basis.

5 Do you see that?

6 A. I acknowledge that's what this
7 says, yes, sir.

8 Q. You don't have any reason to
9 disbelieve the fact that [REDACTED]
10 in this time period was visited by the Ohio
11 Board of Pharmacy on a monthly basis,
12 correct?

13 A. Well, I would have an
14 expectation that there may be some
15 confirmation of that.

16 Q. Did you seek the Ohio Board of
17 Pharmacy records for [REDACTED]?

18 A. I did not.

19 Q. Would one reason for an
20 increase in orders from a pharmacy be when a
21 pharmacy switches orders over from a
22 secondary wholesaler to a primary
23 distributor?

24 A. Just so I understand your
25 question, to terminate their receipt of

1 product from a secondary and go solely to the
2 primary? Is that --

3 Q. Not necessarily terminate. Let
4 me try to clarify the question a little bit.

5 You're familiar with the fact
6 that many pharmacies have more than one
7 distributor?

8 A. Yes, sir.

9 Q. So if a pharmacy shifts its
10 orders of both controlled substances and
11 noncontrolled substances from one distributor
12 to another, the distributor to whom those
13 orders are shifting can expect an increase in
14 volume of controlled substance orders,
15 correct?

16 A. I don't think I understand the
17 question. So the distributions are going to
18 shift from distributor A to distributor B?

19 Q. Yes.

20 A. I don't know that that would
21 cause an increase of the purchases.

22 Q. Well, if -- let's take that
23 simple hypothetical --

24 A. It would be a new distribution.

25 Q. If a pharmacy used to order 50%

1 of its medication from one distributor and
2 50% from another distributor, but then starts
3 ordering 100% from, let's call it distributor
4 X.

5 A. Okay. I understand that
6 hypothetical.

7 Q. Would you expect that
8 distributor X has an increase in the total
9 volume?

10 A. So if I looked at a due
11 diligence file and that situation would have
12 occurred, there should be some kind of review
13 or explanation or due diligence investigation
14 that would be indicative of that occurring.

15 And the other -- the other tool
16 that I might expect to see because there has
17 to be some kind of a review to set a
18 threshold or have an understanding of the
19 legitimate needs of that pharmacy, so I would
20 expect to see some kind of an investigation,
21 maybe obtaining a utilization report or a
22 dispensing report to get a good gauge on the
23 previous patterns of a pharmacy if it's been
24 in existence.

25 Q. Sir, in your report you don't

1 make any reference one way or the other to a
2 shift from secondary distributor to a primary
3 distributor; it's not something that you
4 mention in your report, correct?

5 A. I do not mention in my report,
6 but I am aware that during the time frame of
7 the three registrations, there was some
8 transfers back and forth between suppliers,
9 multiple suppliers, which would be another
10 concern for me as a diversion investigator or
11 for a registrant because --

12 Q. Sir, did you --

13 A. -- that would be --

14 MR. FULLER: Let him finish his
15 answer.

16 A. -- that could be another
17 potential way to camouflage or to stop the
18 review of potential diversion.

19 MR. PYSER: Move to strike the
20 answer as nonresponsive.

21 BY MR. PYSER:

22 Q. In addition to **REDACT**
23 **REDA** in the next paragraph, you make
24 reference to a pharmacy known as CVS
25 No. 3322.

1 Do you see that?

2 A. Yes, sir.

3 Q. And are you familiar with how
4 busy of a store CVS 3322 is?

5 A. I am not.

6 Q. Do you know where it is?

7 A. It's not stated in my report,
8 but I believe it was probably on one of the
9 documents I reviewed.

10 Q. A store that fills between 500
11 and 750 scripts per day of all types of
12 medication, is that a busy store?

13 A. Yes, sir, that's a busy store.

14 Q. Did you review any documents
15 that showed the ratio of controlled
16 substances to noncontrolled substances at
17 CVS 3322?

18 A. So unless you have the due
19 diligence file, I'd like to pull mine out.

20 Q. Happy to show it to you, sir.

21 A. Okay.

22 Q. What's a normal ratio of
23 controlled substances to noncontrolled
24 substances?

25 A. Kind of changed over a period

1 of time. **REDACTED**

7 Q. Are you familiar with the fact
8 that other DEA employees have testified that
9 **R** is the appropriate percentage and have
10 not -- and haven't changed it over time like
11 you just did?

12 A. I don't recall reading any of
13 those depositions. My answer to you would be
14 based on my experience as in the cases and
15 the reviews of records that I've reviewed in
16 regards to those statements by registrants.

17 (Whereupon, Deposition Exhibit
18 Rafalski-18, 7/17/12 Rausch Memo
19 w/Attachment(s),
20 CAH_MDL2804_00000204 -
21 CAH_MDL2804_00000219, was marked for
22 identification.)

23 BY MR. PYSER:

24 Q. I'm showing you what's been
25 marked as Exhibit 18. This is the due

1 diligence file from the CVS 3322 that you
2 reference in your report. And it's in Parma,
3 Ohio, correct?

4 A. Yes, sir.

5 Q. And it's got a series of
6 reports of investigation by Cardinal Health,
7 surveillance reports. Do you see those?

8 A. Yes, sir.

9 Q. And on Bates page ending 209,
10 it gives the address of the store ■ **RE**
11 ■ in Parma, Ohio. **DA**

12 A. Yes, sir.

13 Q. Do you know how close that is
14 to **REDACTED**?

15 A. No, sir.

16 Q. How about **REDACTED**
17 ■

18 A. No, sir.

19 Q. And take another turn of the
20 page to Bates page ending 211.

21 A. Yes, sir.

22 Q. Okay. And here, Cardinal
23 Health writes that the percentage of
24 controlled from this store is 18.4%, correct?

25 A. That's what this document says,

1 yes, sir.

2 Q. You don't have any reason to
3 believe this document is inaccurate, do you?

4 A. Well, my --

5 MR. PYSER: Counsel, why did
6 you just raise your hand in the middle
7 of his answer? He's free to answer
8 the question.

9 MR. FULLER: Oh, because I
10 wanted to answer. Sorry.

11 THE WITNESS: I thought he was
12 going to object. I apologize.

13 A. So when I see this document,
14 what I would expect is to see some document
15 that would corroborate this information. And
16 I don't think in my experience of doing cases
17 that you would just accept that document on
18 face value.

19 I would have -- I would have
20 liked to have seen a confirmation document, a
21 utilization or a dispensing report and some
22 calculations to confirm that these are
23 accurate statements.

24 BY MR. PYSER:

25 Q. Sir, the memo that we're

1 looking at at Bates page 211 states that the
2 purpose of this memorandum is to outline the
3 findings derived from the data provided by
4 CVS, and then it goes on to say the data was
5 based on store-specific averages.

6 Isn't it reasonable to say that
7 Mr. Cameron, who prepared this document, did
8 actually look at that data? Isn't that what
9 he's saying he did there?

10 A. Well, it says data provided by
11 CVS, but it doesn't say what type of data.
12 It could have been a -- just a list of the
13 same information. I didn't --

14 Q. So --

15 A. I would want to see something
16 independent that could verify that.

17 Q. So you're basing your
18 identification of this store as a store that
19 you believe Cardinal Health failed to report
20 to DEA as suspicious over the fact that you
21 don't have the actual data breakdown in the
22 due diligence file even though there's a memo
23 explaining what the data shows, correct?

24 MR. FULLER: Object to form.

25 A. Well, I only see that -- the

1 information provided here. In my report, the
2 concern was a change from a large increase of
3 controlled substances, and I would expect to
4 see some kind of explanation for that
5 increase.

6 BY MR. PYSER:

7 Q. Well, the monthly script volume
8 is 16,778, and the percentage of controlled
9 remains below 20%, correct?

10 A. Yes, but -- but the time frame
11 on this is in November of 2013. The increase
12 occurs in October of 2012. I would expect to
13 see some kind of information relative to that
14 specific increase.

15 Q. You also see the percentage of
16 controlled paid by cash at 2.5%?

17 Do you see that?

18 A. Yes, sir.

19 Q. And that's actually lower than
20 the percentage of noncontrolled paid by cash,
21 correct?

22 A. Yes, sir.

23 Q. So there's nothing suspicious
24 about that, correct?

25 A. Again, I'll make the same kind

1 of assessment that I did earlier. I
2 acknowledge that that is what this says, but
3 I might like to see some kind of other
4 verification that these are accurate.

5 And I make that statement based
6 on my experience with some cases I worked
7 where these type of figures were provided or
8 listed in due diligence but when actually
9 looking at the dispensing reports, that these
10 weren't accurate assessments.

11 Q. Do you know whether Mr. Cameron
12 did look at the dispensing reports?

13 A. I do not know if he did or did
14 not look at them.

15 Q. Do you have any reason to
16 believe that these numbers listed in this
17 document at Bates page 211 of Exhibit 18 are
18 inaccurate? This particular document.

19 A. I'm not going to accept them to
20 accurate because I don't see anything that
21 would be used to verify the accuracy of them.

22 Q. And that's the basis for your
23 criticism, is that the due diligence files
24 don't have all of the information that you
25 believe is appropriate, correct?

1 A. It's not just what I believe is
2 appropriate; it's what I've learned through
3 my training, guidance, distributor briefings,
4 what requirements are required for making
5 these assessments.

6 I think the Masters decision
7 speaks to that too, in regards to verifying
8 information during due diligence
9 investigations.

10 Q. The Masters decision came out
11 in 2017, correct?

12 A. Yes, but that didn't mean --

13 Q. Sir, that was a simple
14 question. I asked for the year. I'm going
15 to ask you to stop opining beyond the
16 question.

17 MR. FULLER: He can provide the
18 explanation he wants to provide.

19 MR. PYSER: He's going well
20 beyond the question. Yes, we have.

21 MR. FULLER: We have this time
22 in deposition, and your witnesses did
23 it and I let them complete their
24 answers. You're going to let
25 Mr. Rafalski complete his answers.

1 MR. PYSER: It's a simple
2 question.

3 BY MR. PYSER:

4 Q. What year --

5 MR. FULLER: He can --

6 BY MR. PYSER:

7 Q. -- did the Masters decision
8 come out?

9 MR. FULLER: He can complete
10 his answers.

11 Go ahead, Mr. Rafalski.

12 A. Do you want me to answer that
13 question or the question prior?

14 BY MR. PYSER:

15 Q. Sir, what year did the Masters
16 decision come out?

17 A. 2017.

18 Q. Thank you, sir.

19 Your report also talks about a
20 CVS Pharmacy No. 219 in Florida, correct?

21 We're going to be on pages 62
22 and 63 now, 63 in particular.

23 A. Yes, sir.

24 Q. Are you aware of the fact that
25 Cardinal Health asked the DEA to investigate

1 CVS Pharmacy 219 in Florida? Did you
2 consider that in your report?

3 A. No, I did not. It doesn't
4 appear in my report.

5 Q. When DEA investigates a
6 pharmacy, do they have the ability to look at
7 the scripts that were filled by that
8 pharmacy, which would include patient and
9 doctor information?

10 A. Yes, sir.

11 Q. When a distributor goes to a
12 customer, to a pharmacy, are they allowed to
13 see the patient information, such as the name
14 of the patient, the doctor, the medical
15 condition for which something might have been
16 prescribed?

17 A. Well, let me just correct my
18 previous statement. I'm not sure that if I
19 went into a pharmacy and reviewed
20 prescriptions I'd see the medical condition.
21 Sometimes there might be a notation. So I
22 want to correct that answer.

23 In regards to my answer to the
24 CVS is they could ask for that information.
25 They don't -- I'm not sure they have a

1 right -- well, they don't have a right to
2 just go in and ask for it. But they could
3 ask CVS to fashion a prescribing report.
4 I've -- I've obtained them in my experience
5 over the years, and minus the patient
6 information, they could get the same kind of
7 information to lead them to make some due
8 diligence decisions in regards to the
9 pharmacy.

10 Q. Sir, are distributors allowed
11 to see patient information that's protected
12 from disclosure by the HIPAA laws?

13 A. No. But it would be easy for
14 them to request a report and not have that
15 information appear.

16 Q. On pages -- so let's return to
17 that.

18 So the report that the
19 distributor could ask for from a pharmacy
20 would have less information on it than the
21 report that DEA would have, correct?

22 MR. FULLER: Form.

23 MR. PYSER: I'll rephrase in
24 response to --

25 THE WITNESS: No, I can answer

1 that question.

2 MR. PYSER: Let me rephrase
3 because your counsel made an
4 objection.

5 BY MR. PYSER:

6 Q. Are DEA investigators able to
7 ask for information that's not available to a
8 distributor when they want to look at a
9 customer?

10 MR. FULLER: Same objection.

11 A. So just the mere ability to go
12 in and look at prescriptions that contain
13 patient information, I would answer yes to
14 that question.

15 BY MR. PYSER:

16 Q. On pages 64 and 65 you list out
17 five pharmacies in a chart.

18 A. Yes, sir.

19 Q. Have you visited any of those
20 pharmacies?

21 A. I have not.

22 Q. Do you know whether or not
23 those pharmacies are active today with active
24 DEA licenses?

25 A. I do not, and I would not have

1 the ability to confirm that.

2 Q. Really? Have you ever heard of
3 Google?

4 A. Yeah, but a Google is not going
5 to give me the DEA registration of those
6 pharmacies. It might list the pharmacy and
7 the name, but that would be an assumption it
8 would have the same DEA number.

9 Q. Is there anyplace where you
10 could go to find out whether a DEA license is
11 still active or not?

12 A. I think there's a service you
13 can subscribe and pay to that you can do
14 that, but I don't pay for that service.

15 Q. Okay. You haven't done that
16 for this case?

17 A. I have not.

18 Q. Earlier today you mentioned a
19 long-term care -- pharmacies that supply to
20 long-term care facilities, correct?

21 A. Yes, sir.

22 Q. Just in simple laymen's terms,
23 what is a long-term care facility?

24 A. That's usually an in-house --
25 not a hospital, but it could be like a

1 long-term care, assisting living center,
2 incapacitated people, senior people, people
3 unable to fully care for themselves.

4 Q. Could it also include hospice
5 care?

6 MR. FULLER: Form.

7 A. That typically wouldn't be
8 referred to as a long-term care facility
9 because hospice is not long-term care.

10 BY MR. PYSER:

11 Q. Do long-term care facilities
12 typically have higher distributions of
13 controlled substances than your average
14 retail pharmacy?

15 MR. FULLER: Form.

16 BY MR. PYSER:

17 Q. In your experience?

18 A. I can't comment one way or the
19 other on that because in my experience
20 there's small to very large. So it's
21 possible for me to answer either way on that.

22 Q. On kind of a percentage of
23 controlled substances versus noncontrolleds,
24 do long-term care facilities have a higher
25 percentage of controlleds than an average

1 retail pharmacy, generally?

2 A. I would say lower, general
3 statement.

4 Q. But there may be exceptions to
5 that?

6 A. Sure, there's always the
7 possibility of an exception.

8 Q. Are distributors allowed to
9 change their policies over time?

10 A. Yes, they are. In fact, I
11 would expect it, as the industry changes and
12 their operations could potentially change.

13 Q. So if you're looking to compare
14 whether a distributor followed its own
15 policies, it would be important to make sure
16 that the policies you're looking at are from
17 the right time period, correct?

18 A. Yes, sir.

19 Q. On page 67 of your report, you
20 discuss 147 suspicious orders for Summit and
21 Cuyahoga Counties from January 1st, 2013 to
22 present. That's in the last paragraph on
23 page 67.

24 A. Yes, sir.

25 Q. Now, in reaching that, you note

1 that -- or you claim that Cardinal continued
2 to ship the same base codes to many of those
3 customers.

4 Do you see that?

5 A. Yes.

6 Q. In reaching that opinion, you
7 assume that every customer had an accrual
8 cycle that ends on the 21st of the month?

9 Do you remember that work?

10 A. I did state that, and I believe
11 I gained that information through a review of
12 one of the depositions.

13 Q. So it's your belief that the
14 21st is the dividing line for Cardinal
15 Health, correct?

16 A. No, sir. I believe that
17 Cardinal Health had, I think, three different
18 dividing lines so that all of the reports --
19 I believe the statement was so that all of
20 the resets didn't occur at the same time. So
21 I think the 21st was the one in the
22 deposition I reviewed for that particular
23 facility.

24 Q. That facility being the
25 Wheeling facility?

1 A. Yes, sir.

2 Q. And that's the basis for your
3 claim here?

4 A. Yes.

5 Q. Okay. You also note that in
6 the 2012 through '15 time frame, a Cardinal
7 Health employee testified that Cardinal
8 Health failed to report to the DEA
9 approximately 14,000 orders it flagged as
10 suspicious across the country.

11 Do you see that?

12 A. What page are you on, please?

13 Q. Fair question.

14 Well, do you remember making
15 a -- drawing a conclusion that Cardinal
16 Health -- here we go -- page 68, last
17 paragraph.

18 Also during the 2012 through
19 '15 time frame, Cardinal's employee testified
20 that Cardinal failed to report to the DEA
21 approximately 14,000 separate suspicious
22 orders.

23 Do you see that?

24 A. Yes.

25 Q. Did you review the letter that

1 Cardinal Health provided to the DEA informing
2 them of this issue?

3 A. I do recall reviewing some
4 documentation on that.

5 Q. So you're aware that not a
6 single one of those orders actually shipped?

7 A. It was my impression from
8 reviewing the documents that they had shipped
9 and they found out of their failure to
10 monitor and post distribution.

11 Q. So it's your belief that some
12 or all of those 14,000 suspicious orders did
13 ship on page 68?

14 A. Hold on one second, please.

15 (Document review.)

16 A. I'd like to review the
17 deposition with the pages, and I didn't bring
18 the depositions, just the other records.

19 BY MR. PYSER:

20 Q. Well, you don't cite in your
21 report to the letter that Cardinal Health
22 provided to DEA informing them of this issue,
23 do you?

24 A. I do not. I cite the
25 deposition testimony.

1 Q. And you also don't cite to
2 Cardinal Health's 30(b)(6) response that also
3 explained that not a single one of those
4 14,000 orders shipped?

5 A. I don't recall ever reading
6 that. I just recall the testimony in the
7 deposition.

8 Q. So you never read the Cardinal
9 Health testimony on behalf of --

10 A. I'm not saying --

11 Q. -- their 30(b)(6) corporate
12 representative on this, correct?

13 A. I'm not saying I didn't read
14 it. I don't recall that statement.

15 Q. Okay. And you don't cite it in
16 the report?

17 MR. FULLER: I'm sorry, I just
18 want to clarify. You said read the
19 deposition testimony. Ms. Norris
20 didn't testify about 14,000 orders. I
21 think a written response was included
22 that may have addressed that.

23 BY MR. PYSER:

24 Q. You never read Cardinal
25 Health's written response that not a single

1 one of those 14,000 suspicious orders
2 shipped?

3 A. I don't have a recollection of
4 reading that document, no, sir.

5 Q. And do you know how many of
6 those 14,000 unshipped suspicious orders were
7 for customers in Cuyahoga or Summit County?

8 A. No, sir. I don't think there
9 was information provided that I could make
10 that determination.

11 Q. So counsel never told you that
12 there were only four unreported unshipped
13 suspicious orders for customers in Cuyahoga
14 and Summit County? They never provided you
15 that information?

16 A. Well, I don't know that it
17 would have or not been provided to me. I
18 don't recall reviewing it myself, no, sir.

19 MR. PYSER: Okay. In deference
20 to my colleagues, I'm going to stop here.
21 I'm not going to ask any more questions. We
22 did not have time to get through all the
23 questions I had for you. Your opinion covers
24 13 separate defendants; therefore, I reserve
25 my right to come back and ask you additional

1 questions at a later point in time.

2 THE WITNESS: Thank you, sir.

3 THE VIDEOGRAPHER: Going off
4 the record, 4:46 p.m.

5 (Recess taken, 4:46 p.m. to
6 4:49 p.m.)

7 THE VIDEOGRAPHER: We're back
8 on the record at 4:49 p.m.

9 EXAMINATION

10 BY MR. EPPICH:

11 Q. Good evening, Mr. Rafalski. My
12 name is Chris Eppich. I represent the
13 McKesson defendant in this litigation.

14 A. Good evening.

15 Q. Thanks for being here today.
16 Mr. Rafalski, you joined the
17 DEA in 2004, correct?

18 A. Yes, sir.

19 Q. Do you have any personal
20 knowledge about McKesson's suspicious order
21 monitoring program from before 2004?

22 A. No, I have no information or
23 knowledge prior to that date.

24 Q. Did you attend the distributor
25 briefing given to McKesson?

1 A. No, sir, I did not.

2 Q. Now, you didn't attend DEA's
3 distributor briefing training until 2008,
4 correct?

5 A. That's correct.

6 Q. Did you have any personal
7 involvement with McKesson's suspicious order
8 monitoring programs before 2008?

9 A. No, sir.

10 Q. What personal knowledge do you
11 have about Mister -- about McKesson's
12 suspicious order monitoring program between
13 2004 and 2007?

14 MR. FULLER: Counsel, when you
15 say personal knowledge, you mean from
16 outside the scope of this litigation?

17 MR. EPPICH: I'm talking about
18 his personal knowledge, his own
19 personal knowledge.

20 MR. FULLER: Object to the
21 form. Anything that you acquired in
22 the scope of work or internal
23 communications, your Touhy
24 authorization doesn't allow you to
25 discuss, unless it's public

1 information.

2 A. I have no knowledge.

3 BY MR. EPPICH:

4 Q. Have you ever visited a
5 McKesson distribution center?

6 A. Yes, sir.

7 Q. When was the first time you
8 visited a McKesson distribution center?

9 A. I've only been there once.

10 Q. When was that, sir?

11 A. I believe it was in early 2014.

12 Q. As a diversion investigator
13 have you ever conducted an audit or cyclic
14 investigation of a McKesson distribution
15 center?

16 A. No, sir.

17 Q. Have you ever interviewed
18 persons in McKesson's regulatory affairs
19 department?

20 A. No, sir. Well, can I maybe
21 make an explanation for that? So when I was
22 on-site, I had discussions with the
23 regulatory affairs person, so I don't know if
24 that would be considered questioning them.

25 Q. Did you -- pardon me.

1 A. But I had some discussion. I
2 don't want to think that -- make sure I have
3 a complete answer that --

4 Q. Did you discuss McKesson's
5 suspicious order monitoring program during
6 that visit?

7 A. I think there was some broad
8 discussion about it.

9 Q. And when would that have
10 occurred?

11 A. 2014.

12 Q. So at least for the time period
13 between 2004 and -- or pardon me, strike
14 that.

15 The opinions that you express
16 in your report for McKesson's suspicious
17 order monitoring program from 1997 to 2007,
18 those opinions are based only on the
19 documents and the portions of deposition
20 transcripts that you reviewed as identified
21 in Appendix I to your report?

22 A. Yes, sir.

23 Q. Let's go ahead and turn to
24 page 70 of your report, sir. Are you on
25 page 70?

1 A. I am, sir.

2 Q. I noticed that your report has
3 page numbers on it. The report produced to
4 us does not have page numbers. When did you
5 last update your report, sir?

6 A. Yeah, I'm aware that you
7 probably have one that does have page
8 numbers, but it has page 1.

9 Q. Yes, sir. They're page 1 all
10 the way down sequentially throughout the
11 report.

12 MR. FULLER: So every page is
13 page 1.

14 A. So when I submitted my report,
15 the explanation that I received, because my
16 original one came back as page 1, is that
17 there was some kind of a conversion to a PDF
18 or something that was done in order to submit
19 it to the court, and that's what caused the
20 pages to change.

21 So subsequent to that, I asked
22 to have one with the page numbers.

23 BY MR. EPPICH:

24 Q. And other than the update of
25 the page numbers to the proper page numbers,

1 are there any other changes between the
2 report that you have in front of you and the
3 report that was produced in this litigation?

4 A. No, sir, I made no changes.

5 MR. EPPICH: I'm going to go
6 ahead and mark as Exhibit 15 the
7 report that was produced in this
8 litigation to counsel.

9 (Whereupon, Deposition Exhibit
10 Rafalski-15, Rafalski Expert Report,
11 was marked for identification.)

12 MR. EPPICH: I'll hand you a
13 copy of that and you can set it aside.

14 BY MR. EPPICH:

15 Q. And simply because we don't
16 have a copy of that report that's in front of
17 you, let's go ahead and mark your binder as
18 Exhibit 17. And we can just mark the outside
19 of the binder -- pardon me, Exhibit 16. And
20 we'll go ahead and give this to the court
21 reporter at the end for copying.

22 Thank you so much.

23 A. Sure.

24 (Whereupon, Deposition Exhibit
25 Rafalski-16, Witness' Copy of Rafalski

1 Expert Report, was marked for
2 identification.)
3 BY MR. EPPICH:

REDACTED



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23 Q. Well, distributors were all
24 receiving guidance from DEA at the same time
25 during presentations and conferences, right?

1 A. Well, that was one of the
2 sources of some of the decisions. I also --
3 my experience says they belong to HDMA, NWDA.
4 I went over -- had various names over various
5 time periods. They were also receiving
6 guidance, I believe, or conducting meetings
7 with them where they were maybe collaborating
8 or sharing information.

9 Q. So if McKesson's Section 55
10 program had been out of compliance with
11 federal regulations and DEA was conducting
12 audits of the McKesson facilities, wouldn't
13 DEA have told McKesson during its annual
14 audits that its program was out of
15 compliance?

16 A. I would have an expectation
17 that if a person was to go on site and
18 actually review the system, that I would have
19 an expectation that there -- maybe should
20 make some comment or do some corrective
21 action.

22 Now, I don't know if an on-site
23 visit, they actually reviewed it and
24 secondly, even if they went on-site and
25 missed it or did review it and issued or made

1 some corrective action, that doesn't mitigate
2 the responsibilities of the registrant.

3 Q. And that's fair, but it's one
4 of the purposes of this audit for DEA to go
5 to the facility of the distributor to review
6 the SOM system and to provide feedback,
7 correction -- corrective feedback to the
8 distributor, if corrective feedback is
9 needed?

10 A. So can I describe a little bit
11 further what an on-site visit is? It's not a
12 checklist type of a visit. It's a
13 three-pronged investigation: security,
14 recordkeeping and accountability. Every DEA
15 investigator conducts it in whatever manner
16 they see fit as long as they cover those
17 three areas or prongs of activity.

18 So it's -- there's nothing in
19 the DEA's requirement that they would
20 specifically have to look at that or take
21 action, although I would say my expectation
22 is they should.

23 Q. Now, you were a DEA diversion
24 investigator between 2004 and 2017, correct?

25 A. Yes, sir.

1 Q. And between 2004 and 2007, you
2 testified that you didn't visit a McKesson
3 facility?

4 A. Yes, sir.

5 Q. Are you aware of any DEA
6 personnel that told McKesson between --
7 between 1997 and 2007 that its Section 55
8 program was violating the CSA and its
9 regulations?

10 A. I'm not aware that anyone ever
11 told them. made that statement to McKesson.

REDACTED

16 Q. Yes, sir. And in not telling
17 McKesson that the DEA believed its system was
18 violating the CSA, was the DEA contributing
19 to the cause of the opioid crisis?

20 A. I don't really have an opinion
21 on that one way or the other. I just want to
22 go back and reaffirm my earlier statement is
23 what the DEA did or didn't do, that didn't
24 diminish or take away the regulatory and
25 legal -- the law requirements for what

1 McKesson should have done.

2 Q. But you have no opinion sitting
3 here today as to whether or not the DEA's
4 failure to tell distributors whether or not
5 their compliance programs violated the CSA
6 contributed to the opioid crisis; is that
7 correct?

8 A. That's an accurate statement,
9 yes, sir.

10 Q. And why haven't you formed that
11 opinion?

12 A. Well, because the corporations
13 or the companies that distribute drugs, their
14 responsibility is clearly stated in the law
15 and within the regulations. If the DEA was
16 to come out and make an error, that doesn't
17 mitigate their needs to make compliance.

18 So -- and along the way,
19 there's -- a lot of times where McKesson gets
20 guidance through industry conferences, I
21 think you stated, distributor briefings, they
22 have the ability to write or ask questions to
23 the policy section of the DEA.

24 So just for clarification, I
25 don't know if anyone ever reviewed or

1 commented on that system, and it doesn't
2 diminish their responsibility under the law
3 and under the regulations.

4 Q. But you agree that DEA is the
5 agency in the federal government that has
6 authority and responsibility for the
7 controlled system of drug distribution in
8 this country, correct?

9 A. In -- yes, sir. In regards to
10 the regulation, they're delegated that by the
11 Attorney General, by Congress to the Attorney
12 General, so I agree with that statement, yes,
13 sir.

14 Q. Let me --

15 A. And let me just clarify.

16 MR. FULLER: Go ahead, finish.

17 MR. EPPICH: I'm really on a
18 limited amount of time here, sir.

19 MR. FULLER: But you can finish
20 and clarify your answer.

21 A. Just a quick clarification. I
22 don't want to misstate. I believe anybody
23 who had anything to be involved with the
24 distribution of controlled substances during
25 this whole time period should have taken

1 positive steps to prevent diversion. I don't
2 want you to think that I don't believe that
3 no one had that responsibility.

4 BY MR. EPPICH:

5 Q. And that would include the DEA,
6 correct?

7 A. Everyone.

8 Q. Is that a yes, sir?

9 A. Yes, sir.

10 Q. And I'd like to go back to our
11 discussion earlier about the do not ship
12 requirements. You're familiar with
13 21 CFR 1301.74(b), correct?

14 A. I am, sir.

15 Q. And that's the one -- that's
16 the one -- that's the -- strike that.

17 This is the regulation that you
18 call the security requirement, correct?

19 A. I don't call it a security
20 requirement. It falls under the security
21 requirements of the CFR.

22 Q. What are the security
23 requirements of the CFR then, if you could
24 list them for us?

25 A. Well, I'd need a CFR. I

1 don't -- a corporate relations --

2 Q. Is there anything beyond
3 Section 1301.74(b)?

4 A. Well, there's many. There's a
5 security requirement just prior to that where
6 it requires a registrant to make a good
7 faith -- a good-faith inquiry before
8 distributing a controlled substance to ensure
9 that the person has a -- as a registrant has
10 a valid DEA registration.

11 There's extensive amount of
12 regulations in regards to security of cages
13 and vaults, very detailed. The type of gauge
14 of wire, the distance of the posts, ceilings,
15 self-closing doors. There's vault
16 requirements, the rebar.

17 It's a whole extensive list of
18 security requirements and the security -- the
19 suspicious order systems within that section.

20 Q. So on page 9 of your report, if
21 you could turn there, we're in Section B
22 under Regulatory Duty?

23 A. Yes, sir.

24 Q. It says: The "security
25 requirement" at the heart of this case

1 mandates the distributors "design and operate
2 a system" to identify "suspicious orders of
3 controlled substances" and report those
4 orders to DEA, quote, the Reporting
5 Requirement, 21 CFR 1301.74(b).

6 In this paragraph, is the
7 security requirement that you're talking
8 about, is that Section 1301.74(b)?

9 A. Yes.

10 Q. Okay. So in the security
11 requirement, my question for you is: Where
12 in the security department does it state the
13 do not ship requirement?

14 MR. FULLER: Form.

15 A. So the overarching right to
16 regulation that's directly controlling this
17 is the maintenance of effective controls to
18 prevent diversion. It would be within that
19 regulation which the do not ship decision --
20 or the do not ship requirement would fall.

21 BY MR. EPPICH:

22 Q. But you agree with me that the
23 security requirement itself does not say the
24 words "do not ship," does it?

25 A. The security requirements do

1 not say those specific three words.

2 Q. And the security requirement
3 does not say "block orders," does it?

4 A. It doesn't -- the security
5 requirement doesn't specifically say that,
6 but as I stated earlier, those are contained
7 within the maintenance of effective controls
8 to prevent diversion.

9 Q. And my question, sir, was just
10 that the words are not used.

11 A. Okay.

12 Q. Okay. If we could turn back to
13 page 40 of your report.

14 A. I'm sorry, what page?

15 Q. 40. I'd like to turn to our
16 discussion of the five methodologies that
17 Dr. McCann used in his analysis. And you
18 mentioned earlier today that you came up with
19 the idea to use those five methodologies,
20 correct?

21 A. Yes, sir.

22 Q. And when did you come up with
23 each of the five methodologies?

24 A. I don't have a specific data.
25 I know that I was told that I would have to

1 come up with five methodologies, so I elected
2 to use the five that I was aware of in
3 conducting this review for my opinion.

4 Q. Who told you to come up with
5 the five methodologies?

6 A. I believe my first conversation
7 about this was with Paul Farrell.

8 Q. And do you recall when that
9 first conversation was?

10 A. I do not.

11 Q. Was it last summer?

12 A. No, it was a little later than
13 last summer.

14 Q. Later than last summer.

15 Did you communicate with any
16 attorneys other than Paul Farrell in coming
17 up with these five methodologies?

18 A. I'm not drawing any direct
19 recollection, but I'm hesitant to just say no
20 because I've talked about this matter, and I
21 would probably say it's more likely than not
22 that I had some conversation about my
23 methodology.

24 Q. And did you have any written
25 conversations or communications about these

1 methodologies with plaintiffs' counsel?

2 A. I don't believe so, telephone

3 conversations.

REDACTED

REDACTED



REDACTED



REDACTED

7 Q. You testified earlier about
8 ARCOS. Are you familiar with the reports
9 generated from the ARCOS database?

10 A. What type of reports are you
11 speaking of, sir? Could you clarify?

12 Q. The reports that a diversion
13 investigator can request from the ARCOS
14 database?

15 A. Oh, so generated pursuant to a
16 request? Yes, sir.

17 Q. Okay. And you saw those kind
18 of reports while you were a DEA diversion
19 investigator, correct?

20 A. I requested those type of
21 reports as a diversion investigator.

22 Q. On page 15 of your report --

23 A. 15?

24 Q. 15.

25 You discuss ARCOS, and in the

1 third paragraph from the top of the page, you
2 say: The ARCOS data, defendant transactional
3 data, and the SLCG reports generated
4 therefrom are consistent with the types of
5 data, facts, information, and reports I would
6 typical rely on in conducting the analysis
7 and reaching the opinions contained therein.

8 Do you see that?

9 A. I do, sir.

10 Q. Now, is it your opinion that
11 Dr. McCann's five threshold-based
12 methodologies can be used to identify
13 suspicious orders under Section 1301.74?

14 MR. FULLER: Form, compound.

15 A. You're asking this question
16 about Dr. McCann in regards to this
17 paragraph?

18 BY MR. EPPICH:

19 Q. I can rephrase it.

20 Is it your opinion that the
21 five threshold-based methodologies used by
22 Dr. McCann and cited by yourself, that those
23 methodologies can be used to identify
24 suspicious orders under Section 1301.74?

25 A. No, I think my opinion is clear

1 that they aren't suitable suspicious order
2 systems.

3 Q. Is it your opinion that
4 Dr. McCann's -- and I quote -- "flagged
5 orders" are suspicious orders under
6 Section 1301.74(b)?

7 A. Are you jumping back to the
8 methodologies?

9 Q. I'm just asking you a question,
10 sir.

11 MR. FULLER: You can clarify
12 the question if you don't understand.

13 BY MR. EPPICH:

14 Q. But, yes, under the
15 methodologies. Under the methodologies, yes,
16 sir.

17 A. No, those aren't suspicious
18 orders under the methodologies. Those are
19 dosage units.

20 Q. While you were at the DEA, and
21 the DEA was analyzing ARCOS data, did DEA use
22 any of Dr. McCann's five methodologies to
23 identify suspicious orders?

24 A. When I was at the DEA?

25 Q. Yes, sir.

1 A. I was gone from the DEA prior
2 to Dr. McCann looking at that data. I guess
3 I don't understand the question.

4 Q. **REDACTED**

■

■

■

8 A. No, sir.

9 DEFENSE COUNSEL: We understand
10 the phone line has been disconnected.

11 MR. EPPICH: Let's go off the
12 record.

13 THE VIDEOGRAPHER: Going off
14 record at 5:13 p.m.

15 (Recess taken, 5:13 p.m. to
16 5:18 p.m.)

17 THE VIDEOGRAPHER: We're back
18 on the record at 5:18 p.m.

19 BY MR. EPPICH:

20 Q. Mr. Rafalski, before the break,
21 we were talking about Mr. McCann's analysis
22 on page 40 of your report. If you could turn
23 there.

24 A. Sure.

25 Q. Earlier today -- let me strike

1 that.

2 You're aware that Dr. McCann's
3 results rest on the assumption the
4 distributors did not conduct any diligence on
5 the first flagged suspicious order, correct?

6 A. Yes, sir.

REDACTED



REDACTED



REDACTED



REDACTED



23 Q. And what is sufficient due
24 diligence in your mind?

25 A. Well, I think it has to be a

1 sufficient investigation to remove any
2 suspicion that the drugs could be potentially
3 diverted and if they're intended for a
4 legitimate source, a legitimate use. So it
5 would be those actions that they would take
6 to be able to confirm that and document it so
7 I would be able to review it.

8 Q. And what is sufficient?

9 A. Well, to merely say increase in
10 volume would not be sufficient due diligence.
11 I think every circumstance is a little bit
12 different, so I guess I would have to look at
13 the records.

14 I don't know that I could say
15 that there's a check -- I could provide a
16 checklist, but I don't know if that would be
17 sufficient, because it's dependent on the
18 scope of the business and what their needs
19 are and what's been established as usual or
20 what's normal.

21 Q. So if McKesson conducted
22 sufficient due diligence on the first flagged
23 suspicious order under its Section 55
24 program, you'd agree that Dr. McCann's
25 analysis is based on a faulty assumption?

1 MR. FULLER: Form.

2 A. Well, if that did occur, then
3 the analysis would stop and it would start
4 again from that point forward.

5 BY MR. EPPICH:

6 Q. You'd agree that at least
7 Dr. McCann's results would change in that
8 circumstance?

9 A. Yes, I would agree with that.

10 Q. And you'd agree that if
11 McKesson conducted sufficient due diligence
12 on the first flagged suspicious order under
13 its LDMP program, that McKesson's results
14 would change, correct?

15 A. I want to clarify my answer on
16 the last one.

17 So I would suspect that in the
18 course of all of the suspicious orders, that
19 maybe there could be one due diligence file.
20 But I think until there would actually be a
21 consistent review of orders -- so -- and I
22 know that probably needs a little
23 clarification.

24 Just say that one employee
25 became very interested and did a thorough due

1 diligence, but that wasn't the program, and
2 it was just one occurrence, then I don't
3 think it's really faulty.

4 I think it requires that the
5 company acted -- actually had to have some
6 procedure in place to actually do due
7 diligence investigations, not just one
8 instance.

9 Q. But in your report you assume
10 that there was no due diligence and that
11 Dr. McCann then relied on that assumption,
12 correct?

13 And so my question is very
14 specific: If McKesson conducted sufficient
15 due diligence on that first flagged order
16 under its LDMP program, its CSMP program, its
17 Section 55 program, you would agree sitting
18 here today that the results that we see from
19 Dr. McCann's analysis, they would be
20 different?

21 MR. FULLER: Object to form,
22 misstates the fact. The witness
23 didn't make the assumption there was
24 no due diligence. He's testified
25 based on his opinion there's not

1 adequate due diligence.

2 A. That's hypothetical. I
3 wouldn't say one -- one due diligence would
4 reset it if the company's conduct continued
5 along the same, the same level, so -- and
6 my -- and my requirement to Dr. McCann was
7 that during the entire time period, I did not
8 see a sufficient due diligence to satisfy the
9 regulatory requirements, so that's why it was
10 ran during the whole time frame.

11 BY MR. EPPICH:

12 Q. How many due diligence
13 investigations or analyses would be enough to
14 be sufficient due diligence?

15 A. Every one of the suspicious
16 orders.

17 Q. Did you review any of the
18 flagged orders from Dr. McCann's analysis of
19 McKesson?

20 A. No, sir.

21 Q. Do you intend to offer any
22 opinions on whether the orders flagged by
23 Dr. McCann are legitimate or suspicious?

24 A. If that requirement is required
25 of me by the attorneys in the case, I would

1 complete that analysis. I don't have any
2 independent intentions of doing that.

3 Q. Sitting here today, you have no
4 opinions about the legitimacy of the flagged
5 orders from Dr. McCann's analysis, correct?

6 MR. FULLER: That misstates his
7 report.

8 A. It's -- Dr. McCann's report
9 doesn't report orders, it just reports dosage
10 units. It doesn't say how many orders. It
11 doesn't say there was an analysis of each
12 individual order.

13 It looked at them whether or
14 not they violated the trigger that was
15 provided for each one of them, and if it --
16 and then it moved forward without the --
17 because already knowing that there was
18 insufficient due diligence.

19 BY MR. EPPICH:

20 Q. And you reviewed -- let me
21 strike that.

22 Let's turn to page 74 of your
23 report. On page 74, I'm looking at
24 Section 6, the second paragraph in
25 particular. The first sentence there says:

1 There is no more effective control to prevent
2 diversion than blocking a suspicious order
3 before it is shipped.

4 Did I read that correctly?

5 A. You did, sir.

6 Q. And that's because a blocked
7 order of opioids remains safely in the vault
8 of the distributor's warehouse, correct?

9 A. I guess you could make that
10 assumption. It doesn't leave the control of
11 the distributor and have the potential to be
12 diverted, so I think that's probably the same
13 statement, yes, sir.

14 Q. You'd agree that reporting the
15 blocked order to DEA in a suspicious order
16 report does not prevent the blocked order
17 from being diverted, correct?

18 A. Well, that hypothetical
19 wouldn't occur because if you block an order
20 and report it, that doesn't -- unless you're
21 saying that that causes a distribution, and
22 if that causes the distribution without the
23 effective due diligence, then no, that would
24 not be true.

25 I would say that it would

1 probably be more prone to be diverted than
2 not diverted because you've already
3 identified it as a suspicious order.

4 Q. Would you agree that a
5 suspicious order monitoring program that does
6 not report suspicious orders but blocks
7 suspicious orders can be effective in
8 preventing diversion?

9 A. It doesn't meet the regulatory
10 requirement.

11 Q. But can it be effective in
12 preventing diversion?

13 A. That's a hypothetical I'm not
14 going to comment on.

15 Q. You don't have any opinion on
16 whether or not a suspicious order monitoring
17 program that does not report suspicious
18 orders but blocks suspicious orders can be
19 effective in preventing diversion?

20 MR. FULLER: Object to form.

21 A. I don't really have an opinion
22 because it's -- it wouldn't be something that
23 would be evaluated as regards to the -- to
24 the regulation.

25 If hypothetically the --

1 McKesson decided not to ship any more
2 controlled substances, that would -- you
3 know, there would be no diversion, so it's
4 just a hypothetical that --

5 BY MR. EPPICH:

6 Q. Yes, and you're an expert in
7 this case, sir.

8 A. I don't have an opinion.

9 Q. So hypothetically, if there is
10 a suspicious order monitoring program --

11 A. Okay.

12 Q. -- that reports a suspicious
13 order -- or excuse me, that does not block --
14 let me strike that.

15 If there is a suspicious order
16 monitoring program that does not report
17 suspicious orders but blocks suspicious
18 orders, that program can be effective in
19 preventing diversion?

20 A. So the mere act of doing that
21 is in violation of the regulation, but the
22 outcome of blocking the order would obviously
23 keep it from being distributed and it would
24 not lead to diversion.

25 Q. Blocking the order of the

1 opioid pills before shipment is what prevents
2 diversion from occurring, correct?

3 A. Yes, sir.

4 MR. FULLER: Form.

5 BY MR. EPPICH:

6 Q. Not the reporting of the
7 suspicious order to DEA, correct?

8 A. But we were discussing the
9 regulatory requirement, so it's to design and
10 operate a system to disclose suspicious
11 orders, and upon disclosure, be reported to
12 the DEA. Under the maintenance of effective
13 controls, it's to stop the shipment.

14 Now, just the mere fact of
15 stopping a shipment when you've identified it
16 as a potential suspicious order would prevent
17 diversion.

18 Q. My question was a little
19 different, and so let me rephrase it.

20 You'd agree that not reporting
21 the suspicious order to DEA is not what
22 causes diversion?

23 A. That's correct.

24 MR. FULLER: Object to form.

25 ///

1 BY MR. EPPICH:

REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED

15 Q. We're going to move on. Let's
16 turn to page 15 of your report.

17 A. 15?

18 Q. Yes, sir.

19 Now, on page 15 of your report,
20 sir, under Section E, the DEA Diversion
21 Investigator's Manual?

22 A. Yes, sir.

23 Q. Your first sentence says: The
24 DEA published a manual which provides further
25 guidance related to the statutory and

1 regulatory duties.

2 Do you see that?

3 A. Yes, sir.

4 Q. The manual you're referring to
5 in that sentence, is that the DEA Diversion
6 Investigator's Manual?

7 A. Yes, sir.

8 Q. You agree that the DEA
9 Diversion Investigator's Manual is not
10 available to registrants?

11 MR. FULLER: Form, misstates
12 the evidence.

13 A. I believe it was provided to
14 registrants.

15 BY MR. EPPICH:

16 Q. So if a registrant asked in
17 1996 for a copy of DEA's Diversion
18 Investigator's Manual, you as a DEA diversion
19 investigator could hand over that manual; is
20 that what you're saying?

21 A. I'm not saying that. I'm
22 saying that I have knowledge that in 1996, a
23 DEA registrant asked -- I believe requested
24 it and it was provided to him.

25 Q. Which registrant?

1 A. Cardinal.

2 Q. Do you have any knowledge of
3 McKesson receiving a DEA Diversion
4 Investigator's Manual?

5 A. No, sir.

6 Q. Now, I'd like to look at the
7 quote that you have excerpted on page 15 of
8 your report. You're familiar with that --
9 with that excerpt, aren't you?

10 MR. FULLER: I'm sorry, what
11 page, Counsel?

12 MR. EPPICH: On page 15.

13 A. The bold section, the italics?

14 BY MR. EPPICH:

15 Q. The entire quote, sir.

16 A. Yes, sir.

17 Q. Do you know where that quote
18 comes from?

19 A. The manual.

20 Q. Which version of the manual,
21 sir?

22 A. I believe the 1996 manual.

23 Q. And it's from Section 5126,
24 Requirements to Report Suspicious Orders; is
25 that correct?

1 MR. FULLER: If you recall. If
2 not, you can pull the document.

3 A. I don't recall specifically.

4 BY MR. EPPICH:

5 Q. Now, the excerpt that you have
6 provided in your report on page 15, this does
7 not say do not ship an order reported to DEA
8 as a suspicious order, does it?

9 A. Doesn't say the terms "do not
10 ship," if that's your question, no, sir.

11 Q. Thank you.

12 MR. EPPICH: Why don't we go
13 off the record for a really quick
14 break.

15 THE VIDEOGRAPHER: Going off
16 the record at 5:43 p.m.

17 (Recess taken, 5:43 p.m. to
18 5:45 p.m.)

19 THE VIDEOGRAPHER: We're back
20 on the record at 5:45 p.m.

21 BY MR. EPPICH:

22 Q. If we could turn to page 10 of
23 your report. On page 10, the first full
24 paragraph at the top of the page says: The
25 regulatory duty not difficult to understand,

1 as one who voluntarily applies to become a
2 registrant must submit an application and
3 undergo a preregistration investigation. The
4 preregistration investigation involves a
5 thorough on-site inspection of the
6 registrant's facilities as well as extensive
7 discussions of the applicable regulations and
8 the security requirements that must be
9 followed.

10 Did I read that correctly?

11 A. Yes, you did.

12 Q. Now, it's true that each
13 pharmacy, distributor and manufacturer must
14 register with the DEA in order to lawfully
15 handle controlled substances in the closed
16 system of distribution, correct?

17 A. Yes, sir.

18 Q. Each pharmacy, distributor and
19 manufacturer must submit an application to
20 DEA?

21 A. Yes, sir.

22 Q. The DEA then conducts an
23 on-site inspection of each applicant's
24 facilities, correct?

25 A. They do not conduct on-site

1 investigations of pharmacies, at least not in
2 the Detroit division.

3 Q. Your testimony here today is
4 that they conduct on-site inspections of
5 distributors?

6 A. Yes, sir, and manufacturers
7 prior to approval of a registration.

8 Q. Why doesn't the DEA conduct
9 on-site inspections of pharmacies?

10 MR. FULLER: Object to form,
11 remind you of your Touhy obligation
12 and internal conversations.

13 THE WITNESS: On advice of my
14 counsel, I'm not going to answer that
15 question.

16 BY MR. EPPICH:

17 Q. Does DEA discuss the
18 regulations and security requirements with
19 each pharmacy, distributor and manufacturer
20 applicant before registration?

21 A. Affirmative to distributors and
22 manufacturers. No with pharmacies.

23 Q. Why doesn't DEA discuss the
24 regulations and security requirements with
25 pharmacy applicants before registration?

1 MR. FULLER: Objection and the
2 same Touhy reminder.

3 THE WITNESS: On advice of
4 counsel, I'm not going to answer that
5 question.

6 BY MR. EPPICH:

7 Q. Now, you're familiar with 21
8 CFR Section 1301.74(a), correct?

9 A. Yes, sir.

10 Q. Now, Section 1301.74(a)
11 requires registrants to check the
12 registration status of its customers before
13 distributing a controlled substance to that
14 customer, correct?

15 A. Yes, I believe it says to make
16 a good-faith effort to check.

17 Q. And DEA conducts all of this
18 diligence on applicants so the distributors
19 can rely on the DEA registrations when
20 complying with 1301.74(a), correct?

21 A. I'm sorry, you have to say it
22 one more time.

23 Q. You'd agree with me that DEA
24 conducts diligence on its applicants so that
25 distributors can rely on the DEA

1 registrations when complying with 1301.74(a)?

2 A. Whether or not they possess a
3 valid DEA registration, is that what you're
4 asking? Yes, sir.

5 Q. Let me make sure my question
6 was clear. You would agree that DEA conducts
7 diligence, reviews applications, looks at the
8 background of these applicants so that
9 distributors can rely on the DEA
10 registrations when complying with 1301.74(a)?

11 MR. FULLER: Object to form.

12 A. So if your question is in
13 regards to pharmacies, they don't conduct
14 those types of investigations, so I'm --
15 maybe I'm still confused by the question.

16 BY MR. EPPICH:

17 Q. My apologies for that.

18 It's true that distributors are
19 to rely on active DEA registrations when
20 complying with 1301.74(a)?

21 A. Yes, sir. They are required by
22 regulation to make a good-faith effort to
23 confirm that the person that they're going to
24 distribute drugs to has a valid DEA
25 registration.

1 Q. And that's actually the only
2 requirement under Section 1301.74(a),
3 correct?

4 A. Yes, it is.

5 MR. EPPICH: Mr. Rafalski, I
6 appreciate your time today. It's been
7 short, and there are a lot of
8 questions that McKesson has for you
9 that we won't be able to get in the
10 brief time I have, so we will reserve
11 our right to return and reopen this
12 deposition if need be. Thank you so
13 much. We're off the record.

14 THE VIDEOGRAPHER: Going off
15 the record at 5:50 p.m.

16 (Recess taken, 5:50 p.m. to
17 5:58 p.m.)

18 THE VIDEOGRAPHER: Back on the
19 record at 5:58 p.m.

20 EXAMINATION

21 BY MR. JONES:

22 Q. Good afternoon, Mr. Rafalski.
23 My name is Scott Jones. I'm going to ask you
24 some questions for my clients, Henry
25 Schein Inc. and Henry Schein Medical

1 Systems Inc.

2 Do you understand that?

3 A. Yes, sir, good evening.

4 Q. Good evening.

5 You mentioned earlier when you
6 were asked to kind of allot the amount of
7 time that you've spent in looking at the
8 various defendants; and you mentioned Henry
9 Schein earlier.

10 Do you remember that?

11 A. Yes, sir.

12 Q. And you mentioned that you
13 hadn't spent as much time looking at them as
14 the other defendants, correct?

15 A. In proportion to the larger
16 distributors, yes, sir.

17 Q. And in your report, you make
18 reference to the CT1 cases?

19 A. Yes, sir.

20 Q. And it's the Track 1 cases?

21 A. (Nods head.)

22 Q. And what do you understand
23 those cases to be?

24 A. Distributions into the two
25 counties, Cuyahoga County and the other

1 county.

2 Q. Summit?

3 A. Yeah, Summit County, thank you.

4 Q. And you understand that each of
5 those is a separate lawsuit and Henry Schein
6 is only named to one of those lawsuits?

7 A. Yes, sir.

8 Q. Do you know which one?

9 A. I don't recall right off the
10 top of my head, no, sir.

11 Q. I'll tell you that's the Summit
12 County lawsuit.

13 A. Okay.

14 Q. If you would, you've got your
15 report in front of you?

16 A. Yes, sir.

17 Q. If you would flip over to
18 page 40 of your report.

19 A. Back to the methodologies.
20 Okay.

21 Q. And down there, Roman numeral
22 III, Identifying Suspicious Orders
23 Distributed in CT1.

24 Do you see that?

25 A. Yes, sir.

1 Q. And then on the next page are
2 these five methodologies, right?

3 A. Yes, sir.

4 Q. And listening today, I
5 understand that these are your five
6 methodologies, correct?

7 A. Yes, sir.

8 Q. You came up with these?

9 A. Yes, sir.

10 Q. And then you applied them --
11 MR. FULLER: Form.

12 BY MR. JONES:

13 Q. -- to particular defendants,
14 correct?

15 A. I'm sorry. Ask that question
16 again.

17 Q. Sure.
18 In looking at pages 41, 42, 43,
19 44, 45 --

20 A. Yes, sir.

21 Q. -- and part of 46, there's
22 charts here laid out under these five
23 methodologies.

24 A. Yes, sir.

25 Q. And these are your

1 methodologies?

2 A. Yes, sir.

3 Q. You came up with these?

4 A. Yes, sir. Well, came up based
5 on the suspicious order systems in place by
6 these registrants, but, yes, sir.

7 Q. Okay. And then you
8 incorporated these into your report?

9 A. Yes, sir.

10 Q. And then you applied them to
11 particular defendants, correct?

12 A. I requested they be applied to
13 particular defendants, yes, sir.

14 Q. Okay. So you -- you selected
15 which defendants are named in each of these
16 tables then?

17 MR. FULLER: Object to form.

18 A. Yes.

19 BY MR. JONES:

20 Q. Okay. And in none of those
21 tables is Henry Schein mentioned, right?

22 A. That's correct.

23 Q. In fact, in each of these
24 methodologies, it's broken out by Cuyahoga
25 County and Summit County, correct?

1 A. Yes, sir.

2 Q. And Henry Schein isn't even
3 named to the Cuyahoga County lawsuit as far
4 as you know, right?

5 A. That's correct.

6 Q. And you've been involved in
7 this case, at least as a consultant or
8 otherwise, since 2017?

9 A. Yes, sir.

10 Q. Did you ever ask, well, why
11 isn't Henry Schein named to both lawsuits?

12 A. I did not, sir.

13 Q. Did anybody come to you and
14 say, hey, do you think we ought to sue Henry
15 Schein in both lawsuits?

16 A. No, sir.

17 Q. And when the opportunity came
18 to amend the lawsuit, did you speak up and
19 say, hey, we ought to add Henry Schein to
20 that lawsuit?

21 A. No.

22 MR. FULLER: Form.

23 A. My capacity, I don't make those
24 kind of decisions or statements.

25 BY MR. JONES:

1 Q. Okay. But you're the -- you're
2 the guy, you're the expert on what's an
3 effective SOM system and what's not an
4 effective SOM system for the plaintiffs,
5 right?

6 A. I am.

7 Q. And there's not another
8 individual who's been designated as an expert
9 by the plaintiffs to help you in analyzing
10 whether or not a SOM system is compliant or
11 noncompliant?

12 A. That is a correct statement,
13 yes, sir.

14 Q. Okay. And sitting here today,
15 you don't know the number of suspicious
16 orders that Henry Schein has distributed into
17 Summit County?

18 A. If you're asking do I have a
19 specific number of orders, I do not.

20 Q. Okay. In fact, you don't know
21 if any suspicious orders have been
22 distributed by Henry Schein into Summit
23 County, do you?

24 A. I don't state that in my
25 report, no, sir.

1 Q. Okay. And similarly, you don't
2 know what, if any, orders that Henry Schein
3 distributed into Summit County were diverted?

4 (Document review.)

5 A. I do not have knowledge of any
6 drugs that were diverted.

7 BY MR. JONES:

8 Q. As part of your work in this
9 case, you reviewed Henry Schein's standard
10 operating procedures?

11 A. Yes, sir.

12 Q. Or SOPs?

13 A. Yes, sir.

14 Q. You also reviewed Henry Schein
15 witness deposition testimony?

16 A. I'm just checking. I don't
17 have a recollection of that.

18 (Document review.)

19 A. Yes, sir, I believe I did.

20 BY MR. JONES:

21 Q. Do you recall whose?

22 A. Abreu.

23 Q. Is that a man or a woman, do
24 you know?

25 A. I don't recall. I remember the

1 name.

2 Q. Okay. And do you know what
3 Abreu's position was within Henry Schein?

4 A. I don't recall.

5 Q. Do you remember -- do you
6 remember anything from reading that witness'
7 deposition?

8 A. I remember the name and looking
9 at some of the -- you know, re-reviewing some
10 of the cites here in the deposition.

11 Q. Okay.

12 A. But I don't have any direct
13 recollection without getting out the
14 deposition and reviewing it.

15 Q. All right. If you would, would
16 you flip over to page 137 of your report, and
17 if you look down, the last full paragraph
18 starting with Orders.

19 Do you see that?

20 A. Yes, sir.

21 Q. And there -- and you wrote
22 this, correct?

23 A. Yes, sir.

24 Q. And there you wrote: Orders
25 that are, quote, identified as suspicious

1 will pend for review, closed quote.

2 A. Yes.

3 Q. And do you have an
4 understanding as to what "pend" means?

5 A. Yes, be held or stop.

6 Q. Okay. Is that like being
7 blocked?

8 A. Yes, sir, that could be another
9 term.

10 Q. Okay. Which is something that
11 you talked about earlier when being
12 questioned by McKesson's lawyer?

13 A. I think I've discussed it all
14 day long, but yes, also with McKesson.

15 Q. I think you have.

16 And if an order is blocked or
17 pend or held, it's not being diverted, is it?

18 A. That's correct.

19 Q. And there you cite -- it's
20 footnote 642.

21 Do you see that?

22 A. Yes, sir.

23 Q. Do you know what you're
24 referencing there?

25 A. I have to get the document.

1 Q. Well, I will tell you that
2 you're referencing a standard operating
3 procedure for Henry Schein. Do you remember
4 the date?

5 A. No, I'd like to get the
6 document.

7 Q. Sure. If you'd like to take a
8 look at it, that's fine.

9 (Document review.)

10 A. 404228 or 4226, I'm sorry?

11 BY MR. JONES:

12 Q. 4228.

13 A. I have 4226. I do not have
14 that document. I'll take a look one more
15 time.

16 Q. I'll tell you what. I'll just
17 tear mine out and we'll use it as an exhibit,
18 if you don't mind.

19 (Whereupon, Deposition Exhibit
20 Rafalski-17, Henry Schein SOP,
21 HSI-MDL-00404226 - HSI-MDL-00404228,
22 was marked for identification.)

23 BY MR. JONES:

24 Q. All right. I'm going to mark
25 as Exhibit 17 kind of a ratty copy --

1 A. That's okay.

2 Q. -- of the document that we've
3 been talking about. Why don't you take a
4 look at that, and just so the record is
5 clear, we're looking at page 137 of your
6 report in connection with the statement that
7 you write: Orders that are, quote,
8 identified as suspicious will pend for
9 review, closed quote.

10 And footnote 642, which
11 references what I've marked as Exhibit 17.
12 Does that comport with your understanding?

13 A. Yes, sir.

14 Q. And can you tell us what that
15 is?

16 A. What this is?

17 Q. Yeah.

18 A. The title is Henry Schein Inc.
19 Verifications, and it says Procedures For
20 Controlled Drug Orders. The date is
21 February 5th, 1998, document number
22 RB-Verification.

23 Q. Okay.

24 A. Approved by and there's a
25 signature.

1 Q. Okay. But that's a 1998
2 standard operating procedure, correct?

3 A. Yes, sir.

4 Q. And that's what you refer to as
5 part of Henry Schein's practice of pending
6 orders that are deemed -- that are identified
7 as suspicious, correct?

8 A. Yes, sir.

9 Q. Okay. And your understanding
10 in looking through Henry Schein's policies
11 and procedures and reviewing the deposition
12 testimony is that Henry Schein would also
13 provide monthly reports to DEA that
14 identified all of the orders pended.

15 Do you remember that?

16 A. Yes, sir.

17 Q. And you're critical of that
18 because that's not done as promptly as you
19 think it should?

20 A. That would be one of my
21 criticisms, that those orders are provided at
22 a time that's after the shipment.

23 Q. No, let's back up a little bit.

24 We just got through talking
25 about how if an order is pended, it doesn't

1 ship, right?

2 A. Yes, sir, maybe I misunderstood
3 the question. I'm sorry.

4 Q. I think you did. I think you
5 did.

6 When Henry Schein sends their
7 pending order reports to the DEA on a monthly
8 basis, those orders are pending, correct?

9 A. Held orders?

10 Q. Yes.

11 A. Yes, sir.

12 Q. So they're not being shipped,
13 are they, pending review?

14 A. That would be a correct
15 assumption of this -- that statement, yes,
16 sir.

17 Q. Okay. And do you know how long
18 Henry Schein provided the monthly pending
19 reports to DEA?

20 (Document review.)

21 BY MR. JONES:

22 Q. If you don't mind, let me help
23 you out just to kind of move things along.

24 A. Sure.

25 Q. If I represented to you that

1 Henry Schein provided monthly pended reports
2 to DEA from the mid to late 1990s up until
3 April 2015, sitting here today, do you have
4 any reason to disagree with that?

5 A. I would have no reason to
6 accept it or disagree with it, sir.

7 Q. Okay. And they stopped in
8 April of 2015. Do you know why?

9 A. No, sir.

10 Q. Would it surprise you to know
11 that the reason why they stopped is because
12 the DEA told them to stop sending them the
13 pended reports?

14 A. That would not -- if your
15 question is would that surprise me --

16 Q. Right.

17 A. -- it would not because if it
18 was a communication to the DEA that was not a
19 suspicious order and it was a held order, I
20 would -- I would believe that the DEA would
21 want a report of suspicious orders.

22 Q. Okay. Do you know whether or
23 not as part of the pended order reports that
24 were delivered monthly also included a list
25 of those orders deemed suspicious following

1 Henry Schein's investigation?

2 A. Let me see if I state that in
3 my report. I don't have independent
4 recollection of that.

5 Q. So you don't know one way or
6 the other?

7 A. No, I'm not saying that.

8 Q. Okay.

9 A. I'm just saying I don't have a
10 direct recollection when you state it that
11 way.

12 Q. How is that different than what
13 I asked? Let me back up then.

14 Sitting here today, do you know
15 one way or the other whether or not Henry
16 Schein provided monthly suspicious order
17 reports along with the pended order reports?

18 A. The statement I make in my
19 report is for the time period of 2009 to
20 2018, that there were no suspicious orders
21 reported in the CT1 jurisdiction.

22 Q. Well, I know -- I --

23 A. I --

24 Q. Mr. Rafalski, I get that.

25 A. Okay.

1 Q. I mean, but that's specific to
2 Summit County, isn't it?

3 A. Yes, sir.

4 Q. That doesn't pertain to Henry
5 Schein and how they do business elsewhere,
6 does it?

7 A. It does not.

8 Q. And you're familiar with Craig
9 McCann's characterization of Henry Schein's
10 business in Summit County, are you not?

11 A. No, I'm not sure what statement
12 you're making there.

13 Q. Okay. Are you familiar with --
14 do you know that he gave a deposition last
15 week?

16 A. I -- he did give a deposition.

17 Q. And you probably haven't had a
18 chance to review the testimony yet, have you?

19 A. I have not.

20 Q. Have you had a chance to talk
21 to him about it?

22 A. No, sir.

23 Q. Would it surprise you to know
24 that he characterized Henry Schein's dealings
25 with Summit County as de minimis?

1 A. I would have no reason not to
2 believe your statement that that's what he
3 said.

4 Q. Do you know if DEA has ever
5 expressed any criticisms about Henry Schein's
6 suspicious order monitoring system?

7 A. I'm not aware of any
8 communication from the DEA to Henry Schein in
9 regards to that topic.

10 Q. Mr. Rafalski, can reasonable
11 minds disagree as to whether or not an order
12 is suspicious?

13 A. I think there's always the
14 potential for a disagreement of -- if you're
15 talking about designing a system and what's
16 suspicious. I think it's the subsequent due
17 diligence that confirms or not the accuracy
18 of whether or not an order is suspicious.

19 So just the nature of an
20 agreement or disagreement on what defines a
21 suspicious order, you mean the definition of
22 it or what it is, I guess?

23 Q. Can reasonable minds disagree
24 as to whether or not a particular order is
25 suspicious?

1 A. I think, yes, I would answer
2 yes to that question.

3 MR. JONES: All right. No
4 further questions. I'll pass the
5 witness. Thank you.

6 THE VIDEOGRAPHER: Going off
7 the record at 6:16 p.m.

8 (Proceedings recessed at
9 6:16 p.m.)

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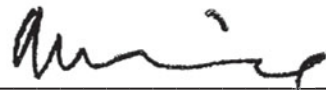
CERTIFICATE

I, MICHAEL E. MILLER, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that prior to the commencement of the examination, JAMES E. RAFALSKI was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that pursuant to FRCP Rule 30, signature of the witness was not requested by the witness or other party before the conclusion of the deposition.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.



MICHAEL E. MILLER, FAPR, RDR, CRR
Fellow of the Academy of Professional Reporters
NCRA Registered Diplomate Reporter
NCRA Certified Realtime Reporter
Certified Court Reporter

Notary Public

My Commission Expires: 7/9/2020

Dated: May 15, 2019

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it.

10 You are signing same subject to
11 the changes you have noted on the errata
12 sheet, which will be attached to your
13 deposition.

14 It is imperative that you return
15 the original errata sheet to the deposing
16 attorney within thirty (30) days of receipt
17 of the deposition transcript by you. If you
18 fail to do so, the deposition transcript may
19 be deemed to be accurate and may be used in
20 court.

	ERRATA		
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1 ACKNOWLEDGMENT OF DEPONENT

2
3
4 I, JAMES E. RAFALSKI, do hereby
5 certify that I have read the foregoing pages
6 and that the same is a correct transcription
7 of the answers given by me to the questions
8 therein propounded, except for the
9 corrections or changes in form or substance,
10 if any, noted in the attached
11 Errata Sheet.
12

13 _____
14 JAMES E. RAFALSKI

DATE

15 Subscribed and sworn to before me this
16 _____ day of _____, 20 ____.

17 My commission expires: _____
18

19 _____
20 Notary Public
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	LAWYER'S NOTES		
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